DOCUMENT RESUME

ED 317 377 SE 051 265

TITLE Health Care Innovation: The Case for a Favorable Public Policy.
INSTITUTION Merck & Co., Inc., Rahway, NJ.
PUB DATE Aug 88
NOTE 76p.
PUB TYPE Reports - Evaluative/Feasibility (142) -- Viewpoints (120)

EDRS PRICE MF01/PC04 Plus Postage.
DESCRIPTORS *Biomedicine; *College Science; Educational Improvement; Government Role; *Health; Higher Education; Industry; Innovation; Intellectual Property; *Medicine; *Public Policy; Required Courses; *Research and Development; School Business Relationship; Science Education; Science Teachers; Secondary Education

ABSTRACT

Much of U.S. public policy reflects what is valued most in the United States--entrepreneurship, the productive interaction of market forces, individual achievement, and inventiveness. It appears to some that the United States has become preoccupied with short-term concerns and has not been acting with its accustomed determination to maximize opportunity. This booklet was published in an attempt to refocus public attention on the conditions that foster innovation in the medical field. The following elements are discussed in detail: protection of intellectual property, regulatory review, tort law, research and development, science education, and tax policy. The main emphasis is on the impact of these areas on biomedical technology. In particular, this report highlights the decline in the proportion of undergraduates receiving science and engineering degrees in the United States. It is recommended that federal support for science education be increased, minimum standards for science and mathematics in schools be increased, public education be modernized, and existing programs be strengthened. The need for partnerships between schools and industry is stressed. (CW)

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Our century has witnessed the greatest advances in scientific knowledge and technological innovation in human history. We have conquered smallpox, unleashed the promise of agriculture and gained insight into stucture of matter. The laser and computer, the semiconductor and recombinant DNA – all are fruits of modern science. In a supreme tour de force, we went to the moon. Although scientists worlwide fueled this engine of knowledge, over the past four decades, science has been dominated by Americans. ... [And] the basis of this spectacular burst of American scientific achievement is a research partnership among universities, industry and the Federal government.

John Brademas
President, New York University

Competitiveness and technological innovation have become popular phrases today as both the public and private sectors have been forced to confront the country's budget and trade deficts. They seem appropriate because our nation has historically drawn upon an ability to improve a product, streamline a process, or get a new idea off the drawing board and into the marketplace. We have benefited by American creativity in the past, and we probably need it now as much as any time in our history.

Representative Thomas Foley (D-WA)
House Majority Leader

One of the most important elements of America's economic success has been our scientific and technological innovation. The new products and improved processes developed by American researchers have benefited not only the United States, but the world.

Senator Robert Dole (R-KS)
Senate Republican Leader

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Kerry Cancro looks on as Dr. K.R. Weignarajan, Bayonne, N.J., vaccinates her four-year-old daughter, Kristina.

PUBLIC POLICY AND BIOMEDICAL INNOVATION

Like most research-intensive pharmaceutical firms, Merck stands or falls on its ability to generate important new medicines year after year. In short, on its sustained ability to innovate.

Normally, a research-intensive pharmaceutical company does well to market one major new medicine every few years. Over a two-year period, 1986-87, we introduced seven: treatments for ulcers and urinary tract infections, a powerful multipurpose antibiotic, the first genetically engineered vaccine and three new cardiovascular drugs, including a breakthrough therapy for lowering cholesterol in the bloodstream.

Innovation on that scale does not occur in a vacuum; it depends on a mutually beneficial interaction with society. That's why we at Merck are committed not only to being innovative ourselves but also to helping assure a national and world environment that appreciates and highly values innovation.

As home base for an innovative company, the United States has much to offer.

This country strongly protects patents and other forms of intellectual property. Without such protection, investment in research and development would shrink, and the flow of new medicines, among other innovations, would slow to a trickle. In our industry, as in all others, patent protection is the bedrock of innovation.

Through voluntary contributions from individuals and businesses, as well as through Federal tax dollars, Americans strongly support basic research and post-graduate education. In the biomedical field, the National Institutes of Health and the nation's great research universities continue to attract brilliant young people (many of whom will be our future employees) from around the world. No wonder Merck spends 75% of all its research funds and 80% of its basic research funds here in the United States.

Americans know the value of good medicine. They realize that pharmaceutical innovation saves lives, relieves suffering and cuts medical costs by keeping people out of operating rooms, hospitals and doctors' offices. They know that pharmaceutical innovation can not only lengthen life but help make it more worth living.

By and large, the U.S. government has translated public appreciation into constructive public policy. The financial risks inherent in our business are extraordinary. Yet, despite the risks and the historical ups and downs of individual firms (including Merck), the industry has continued to contribute to society and thus to grow.

The opportunity to earn a significant profit remains the key to attracting investment in an industry facing heavy odds against success. The financial incentive, combined with scientific advances permitting progress against disease, has enabled the American pharmaceutical industry over time to become the world leader.

But, in recent years, evidence has been mounting that the environment for industrial innovation in the United States is not all it should be. Much smaller nations, relatively poor in natural resources, have displaced this country from its position as the world's foremost industrial state. The American standard of living has begun to slip — not just comparatively but absolutely. U.S. workers are no longer the world's best paid. Japanese and German workers are.

It has been argued that much of the responsibility for the decline rests with business management. But now, with management moving decisively to correct its shortcomings, it is time to look more closely at the other side of the equation, the environment of public policy.

No policy has discouraged industrial innovation in this country more than allowing the Federal budget a free rein. The U.S. budget deficit remains probably the single greatest threat to economic health and industrial innovation — not just in this nation but around the world.

Although the U.S. strongly protects intellectual property within its borders, the nations of the world have yet to devise an effective system for protecting such property globally. Public attitudes and policies that tolerate less than full participation in efforts to form such a system allow commercial pirates to siphon off billions of dollars and thousands of jobs from the U.S. economy every year.

In the Food and Drug Administration (FDA), U.S. public policy has created one of the world's most respected and sure-handed regulators. But FDA is also among the world's slowest regulators because it is denied the resources it needs to do its job with dispatch. No factor is more vital to safety, for in medicine unavailability can be just as fatal as toxicity or ineffectiveness.

Innovation is also hampered by Congressional reluctance to address the product liability crisis. In the health care industry alone we have already seen a vaccine shortage, refusals by physicians to vaccinate and curtailment of research in medical fields susceptible to litigation.

This nation's capacity for bringing discoveries and ideas to economic and social fruition remains comparatively undeveloped. How can the United States, with its tradition of trickle-down technology, hope to compete successfully with trading partners that identify the transfer of technology from the laboratory to the marketplace as a national goal?

In spite of having universities and research institutions that remain the envy of the world, the United States is clearly failing to make its youth scientifically and mathematically literate. Nor is it even awakening their interests in these fields. Increasingly, by default, their places in America's graduate schools are being taken by the foreign-born. No advanced nation can afford a public policy that neglects basic education.

Tax policies can be powerful incentives or disincentives to innovation. Permitted to change with the wind or work at cross purposes, they all function as disincentives.

Much of U.S. public policy today reflects what Americans value most — entrepreneurship, the productive interaction of market forces, individual achievement and inventiveness. But Americans have also become preoccupied with short-term concerns. Industrially, the United States has not been acting with its accustomed determination to maximize opportunity. Out of anxiety to make sure that nothing goes wrong, public policy has failed to make sure that enough goes right.

Hence this booklet, which we publish in the hope that it may help refocus public attention on the conditions that foster innovation. Without making any claim for comprehensiveness, the booklet looks in some detail at the following policy elements:

- Protection of intellectual property
- Regulatory review
- Tort law
- Research and development
- Science education
- Tax policy

Although biomedical innovation receives special emphasis here, much of the content applies with equal force to industrial innovation of all kinds.

We hope you find this presentation useful, both as a source of facts and a stimulus to dialogue. We welcome your comments and suggestions.

Sincerely,

P. Roy Vagelos, M.D.
Chairman and Chief Executive Officer
Merck & Co., Inc.

August, 1988

If we are to have an acceptable future in an increasingly technological and competitive world, and if we are to respond adequately to national needs in areas of economic competitiveness, national security and quality of life for all our citizens, the time has come when a new partnership involving . . . the Federal government, universities and the private sector must be forged.

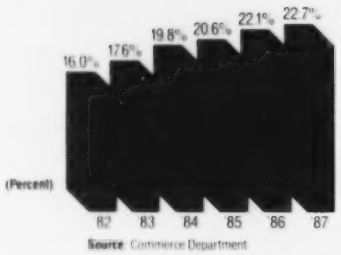
Report of the White House Science Council, February 1986

Technological innovation, many economists believe, is responsible for nearly half the increase in United States productivity over the last 40 years, and some would argue that the proportion is two-thirds or more. In the last 20 years alone, innovation has accounted for nearly 40% of the growth in the nation's GNP (Gross National Product).

This technological productivity has been achieved by industry in a synergistic partnership with government and academia. Government has funded primarily basic research — the kind that advances fundamental knowledge — through a network of Federal laboratories, such as the National Institutes of Health (NIH), and through grants to academic investigators. Industry has been primarily responsible for applied research — the kind that uses fundamental knowledge to develop commercial products and services. When the government funds applied research, it is usually military in nature or a specific mission-related project too large for industry to manage on its own, such as putting a man on the moon. Unlike other nations that invest in industrial growth, the U.S. has been reluctant to spend public funds on the commercialization of technology — that is, the efforts needed to bring the products of technology to the marketplace quickly and efficiently.

The traditional American reliance on industry initiative and market forces to spur commercialization has worked well in the past. U.S. scientific achievements set a standard for the rest of the world. The country's entrepreneurial spirit has generated an unprecedented number of new industries that have fueled the nation's economic growth and benefited people throughout the world.

FOREIGN GOODS IN U.S. MARKET



Foreign products' share of domestic market excluding oil, corrected for inflation.

Source: Commerce Department

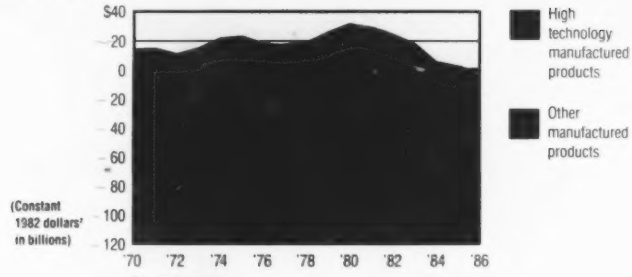
Other industrialized nations, such as Japan, Germany, France and the United Kingdom, have developed a different policy. Because they have seen commercialization as essential to their economic survival, they have developed government agencies and policies to bring it about as rapidly, efficiently and certainly as possible. This is particularly true for nations that, with American assistance, have had to rebuild their economies following World War II. Today they are major powers in the international marketplace. Over the course of these four decades, the world, and America's place in it, have undergone radical changes. The vision of the world as a "global village," articulated in earlier decades, has become more of a reality. Nations are linked by the flow of information, investment, research and technology as never before. Joint ventures that cross international borders are common.

Although some may wish to erect barriers, the movement toward greater cooperation is most welcome. Global innovation has produced benefits for every nation and must be encouraged everywhere. Each country sets its own agenda for succeeding in today's international market, and a number have developed effective public policies to achieve that goal. American policymakers have also begun to evaluate their options to determine how to prevent stagnation and spur continued growth. Americans have been slow to realize the impact of these changes in the global market on the domestic economy, but it is profound. Foreign products represent a growing share of the U.S. domestic market: they increased from 16% in 1982 to 22.7% in 1987. America has lost leadership in mass manufacturing, which the nation pioneered. The consumer electronics industry, developed in the U.S., has moved elsewhere. In 1986, the United States registered a trade deficit in high-technology industries for the first time.

Other nations are nurturing scientific establishments that rival that of the U.S. Data indicate that although U.S. investment in R&D remains substantial, the locus has shifted. More science and technology are now being generated outside the country. In 1970 the U.S. performed about 60% of all R&D in the OECD (Organization for Economic Cooperation and Development) countries, which, in addition to the U.S., include Canada, the nations of Western Europe, Australia, New Zealand and Japan. Today this percentage is believed to be less than half.

American scientists continue to maintain an excellent record of research achievements, contributing significantly to advances in worldwide scientific and technical

U.S. TRADE BALANCE[1] IN HIGH-TECHNOLOGY AND OTHER MANUFACTURED PRODUCT GROUPS



[1]Exports less imports.
[2]GNP implicit price deflators used to convert current dollars to constant 1982 dollars.

Source: Science & Engineering Indicators–1987

knowledge. U.S. researchers earn an impressive share of Nobel prizes and write a substantial portion of all scientific and technical articles published. But, as the following examples illustrate, these achievements alone will not ensure technological success in world markets.

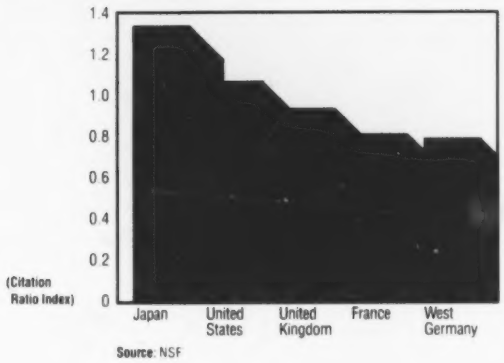
Although American universities and research institutions are first-rate, attracting the best and the brightest from throughout the world, American primary and secondary educational systems are proving grossly inadequate in training students for scientific and technological fields. Foreign-born researchers have contributed significantly to the U.S. basic and applied research establishment, and the country is fortunate that they choose to study and teach in America; however, native talent is not being cultivated. Moreover, facilities for teaching and research are woefully out-of-date. If current patterns persist, not only will America not meet the demand for a skilled resident work force, but the nation will fail to create a technologically literate society capable of making judgments on such complex issues as the environment, defense, energy and biotechnology.

"American scientists are the best researchers in the world, but too often we have lost control over technological innovation. There is a big gap between the petri dish and the production line. Our competitors make that transition very well. We must do better, by supporting applied research . . . . We need to develop a long-term research and development agenda for the future."

Representative John D. Dingell (D-MI)

A second area of concern is patents, a primary indicator of potential technological achievement. Although American inventors have in previous years earned more patents than the rest of the world combined, the gap is closing rapidly. The U.S. is being overtaken more than just numerically. A 1988 National Science Foundation-sponsored (NSF) study that analyzed not the quantity of a nation's patents but their innovative quality produced some surprising results. Using an experimental methodology that measures the frequency with which a patent is cited by other inventors, researchers found that as early as 1976 Japanese-held patents were cited more frequently than those granted to Americans. The study also reported that the Japanese patents focus on the most promising areas of economic growth, such as semiconductors, photography, automotive technology and pharmaceuticals.

PATENTS: AN INDEX OF INNOVATION

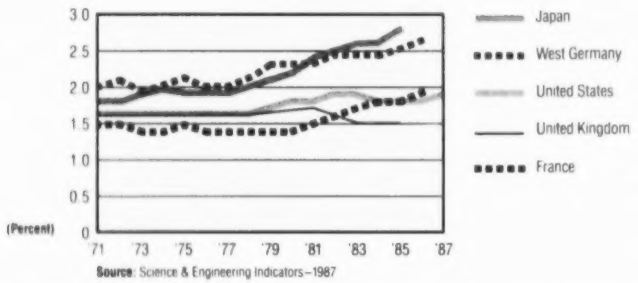


A 1988 NSF-sponsored study analyzed patents granted between 1976 and 1985, for the purpose of comparing nations as to industrial innovativeness. The study began by ranking patents according to the number of times they were cited by other inventors. A score of 1.0 on the chart (the 10% most-cited patents) was considered to be as innovative as might be expected, or "average." At 1.34, Japan was 34% above average. The only other above-average nation in the study was the U.S., with an index of 1.06, or 6% above average.

The emerging pattern has led many to reevaluate the effectiveness of the traditional public-private partnership in America. Although each nation evolves a policy for economic growth based on its particular history, culture and value system, it may be useful to examine the ways in which other nations have addressed these problems in order to gain a better perspective on America's own.

For example, although total U.S. spending for R&D as a percent of GNP is similar to that of Japan and West Germany, the share these two countries spend on non-defense R&D is noticeably larger. According to the NSF, Japan and Germany spend 2.8% and 2.6% respectively on non-military R&D, whereas the U.S. spends only 1.8%. Japan, Germany, France, the U.K. and Sweden all spend larger shares of their R&D funds on non-defense R&D than the U.S. And not surprisingly, the U.S. spends the lowest proportion on R&D directly related to non-military industrial growth.

NON-DEFENSE R&D EXPENDITURES AS A PERCENT OF GNP, BY COUNTRY



As the statistics suggest, the governments of other countries are committed to explicit support for commercialization of technology, and not just in funding. To further their national economic objectives, other nations have made the implementation of this goal a public policy priority. In Japan, for example, three ministry-level offices are charged with developing different aspects of science and technology.

Comparative data on government R&D funding by objective for a year in the 1983–86 period, depending on country and item

Objective	U.S.	Japan	FRG	France	U.K.	Sweden
Defense	69%	3%	12%	31%	52%	26%
Advance of knowledge*	4	54	44	27	22	43
Space	5	5	5	6	2	3
Energy	4	14	11	7	5	6
Health	10	3	3	4	4	1
Industrial growth	0.2	6	14	13	7	6
Agriculture	2	11	2	4	5	3
All other	6	4	9	8	3	12
Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**

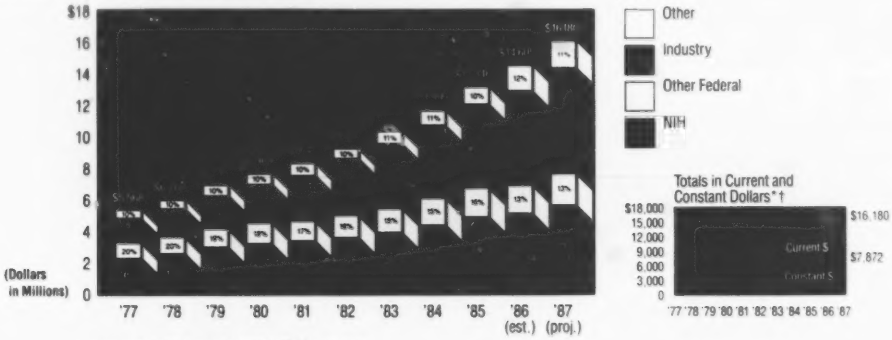
*General purpose research, including an estimated portion of general university funds (except U.S.) For the United States, only general research not supported for the other objectives is reported here.

Source: Leonard L. Lederman, head of the Special Analytical Studies Section, Division of Science Resource Studies, National Science Foundation

Despite the lack of explicit support for commercialization in the U.S., and despite the rapid gains made by the Japanese in this field, the health care industry is one area where America has been able, so far, to keep pace. Health-related R&D spending, which represents just under 13% of total U.S. government and non-government research expenditures, presents a positive picture. Totals have increased steadily over the years: in 1987, the NIH estimated this figure at $16.2 billion, nearly $2 billion over 1986 figures. No other country spends as much.

Funding for health-related R&D is shared by the Federal government, with some state and local help, the pharmaceutical industry and private, nonprofit health organizations. Together, government and industry now invest about $15.5 billion annually — Federal and state government just over $8.7 billion ($5.5 billion through the NIH), industry just over $6.8 billion. The health organizations contribute another $ .7 billion.

NATIONAL SUPPORT FOR HEALTH R&D BY SOURCE, 1977–1987



*Constant dollars based on biomedical R&D price index.
†FY 1977 = 100. Projected to 205.54 for 1987, based on percentage increase in estimated GNP implicit price deflator.

Source: NIH

The health care industry provides an excellent example of both the human and economic value of innovation. As is true for much of the private sector, the industry funds its own applied research, albeit at considerable risk. The process is lengthy, and the costs are staggering. Research in this high-technology age requires highly skilled scientists in a variety of disciplines, carefully controlled laboratory environments and state-of-the-art computers and instruments. It takes an average of 7 to 10 years and close to $125 million to bring a new medicine from laboratory to market. Most product candidates fall by the wayside.

Despite these obstacles, pharmaceutical research has succeeded in generating great medical benefits: vaccines to prevent measles and hepatitis . . . cures for tuberculosis, pneumonia and other diseases of past decades . . . progress against cancer and heart disease . . . longer life expectancy — 54 years for an American born in 1920, 75 years for one born today.

"To a great extent, the United States and its people enjoy our present stature because of our success in transferring science into technology."

Senator John Danforth (R-MO)

Pharmaceutical innovation has also demonstrated great social and economic value. In 1983, the U.S. Centers for Disease Control conducted a study of benefits, risks and costs associated with immunization against measles, mumps and rubella (German measles). On the basis of prior trends, the CDC estimated that without an immunization program there would have been more than three million cases of measles in the United States in 1983. With vaccination, there were only about three thousand cases. Similar declines were reported for rubella and mumps.

The most important results were in the saving of children's lives and prevention of the brain damage and loss of sight and hearing that can accompany these ailments. But there is also a cost-effectiveness story that deserves to be told. The CDC estimated that costs resulting from these three diseases — without vaccination — would have totaled $1.4 billion in 1983. Vaccination costs totaled less than $100 million, thus yielding a benefit-to-cost ratio of 14-to-1.

While the primary goal of medical research is to save lives and ease suffering, it can also save health care dollars. The costs of disease are far greater than the cost of drug treatment. In 1980 alone, for example, the costs of cardiovascular disease included 50.7 million hospital days, 900 million disability days and $33 billion in medical care expenditures, not to mention the countless potential years of life lost before the age of 65. New medicines have steadily displaced more expensive forms of health care. Medication can, for example, reduce the need for coronary bypass surgery and prevent second heart attacks.

As America ages, the need for ways to extend not only life expectancy, but *active* life expectancy, becomes a priority in terms of both human and economic value. It is estimated that a medicine that can cure Alzheimer's disease has the potential to save the U.S. $50 billion a year and to reduce the nursing home population by at least one-half.

The pressures generated by today's fiercely competitive global market place a high economic priority on the creation of a more favorable climate for biomedical and other research and development.

The steady upward pattern of funding for basic research is a positive sign, but funding alone is not the answer. A chief priority must be to link America's scientific and entrepreneurial capabilities to the goal of economic growth by learning to

translate innovative ideas into manufactured products quickly and cost-effectively. The Technology Transfer Act of 1986 and the National Science Foundation-sponsored Engineering Research and Science and Technology Centers — cooperative ventures between industry and academia under the aegis of government — are positive steps. Achieving the full intent of these and similar initiatives is critical to the nation's future.

"America's future depends in part on the ability of its industry to embrace change. Industries throughout the nation need to be open to new technologies, new markets and new opportunities. One of the cornerstones in our ability to embrace change is investment by the government, academia and industry in R&D."

Senator Bill Bradley (D-NJ)

What is needed now is not another megaproject, nor a fashionable buzzword that will be old hat tomorrow, but a new set of public-private sector relationships that will guide day-to-day decisions in education, business and public policy.

America must create some means of gauging the effect of fiscal and trade policies on innovation — the support they provide or the barriers they raise — at the highest levels of government to permit informed decision making on these issues.

Regulation is another key area with great impact on the ability to innovate. Although this booklet's chapter on regulation deals primarily with the Food and Drug Administration's approval process, there are other areas — animal research and biotechnology, for example — where regulation can help or hinder innovation.

It is also important to measure the impact of such issues as protection of intellectual property and the need for tort reform, and most people agree that it is long past time to repair our ailing educational system.

This booklet examines these specific concerns. It is important to note that although we support innovation throughout the world, we have concerned ourselves only with U.S. policy in these pages. Our goal is to help policymakers channel America's extraordinary capacity for discovery and invention toward a national purpose — economic strength and growth in today's global marketplace.

As Robert M. White, president of the National Academy of Engineering and former head of the National Oceanic and Atmospheric Administration, summarized it:

> Markets for goods and services are now [as] global as . . . the science and engineering enterprise itself. No matter the height of political and economic barriers we may erect, . . . domestic markets have become political artifices . . . . There is no place to hide. All industrial firms must be competitive in the global economy even if they only serve domestic markets. Every nation must now be intellectually and innovatively competitive for economic survival.

I. PROTECTING INTELLECTUAL PROPERTY

No property is more valuable to the economies of highly developed nations — or to the health and well-being of humanity — than intellectual property. Yet none is more vulnerable to theft. Rights to patents, trademarks, copyrights and other forms of intellectual property are generally well protected in the United States. Abroad, however, the absence of universal standards of protection and the unevenness of law enforcement drain billions of dollars annually from the U.S. economy, shrink overseas markets for U.S. products, put Americans out of work and reduce funding for the research and development on which the future of all mankind depends.

The Constitution of the United States (1787), Article I, Section 8: "The Congress shall have power To . . . promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . . ."

Inherent in a book, a trademark or a medicine are values that vastly exceed those of the objects themselves. A book may embody an artistic reputation springing from a lifetime of devotion to the writer's craft. A trademark may represent a century or more of hard-won public trust and customer loyalty. A medicine often embodies technological advances wrested from decades of research and hundreds of millions of dollars in high-risk investments.

The pirates who steal these priceless intangibles easily find ways of profiting from their misuse. Trademarks are copied. Films, books, recorded music and computer programs are duplicated inexpensively with no loss of fidelity. A medicine that resulted from the work of hundreds of Ph.D. scientists and M.D. clinicians, and took years to win regulatory approval, may be copied inside of a week by a single chemist with little more than a master's degree. The patent holder will be unaware that a theft has occurred until the product of the theft appears on a market. And within a year, the pirate may be able to produce enough to drive the patent holder's product from that market.

Punishment for economic piracy is far from certain. Some countries simply have no laws at all to protect intellectual property. Others have laws but may fail to prosecute pirates. Still others explicitly exempt medicines and other products

from patent protection for "humanitarian" reasons. Even in advanced nations like the United States, legal loopholes may have left certain kinds of intellectual property, such as process patents, less than adequately protected.

Who wins and who loses from piracy? And why is protection of intellectual property so important to the United States and to the international trading system?

Newly developing and industrializing nations may *believe* they can win with piracy. It enables them to buy and make high-tech products such as medicines and videotapes at low prices. It enhances the attractiveness of their exports, improving their balance of trade. Medicines made from stolen intellectual property can often save lives and relieve suffering just as well as those acquired honestly. Why not let the nations that can afford to do research pay for it?

What such rationalization overlooks, of course, is that everyone benefits from industrial innovation wherever it occurs. New, more cost-effective, environmentally benign technologies for producing power and food, new technologies of transportation and communication, and new lifesaving medicines are in everyone's interest. Ironically, the countries where the protection of intellectual property rights is weakest are those where 20 million people die of starvation-related causes each year and 700 million more suffer from severe malnutrition. These are the countries that would benefit the most from innovation in agriculture and medicine.

Piracy also invites economic retaliation. It tends to turn its victims into protectionists and advocates of selectively punitive trade measures.

Finally, since piracy and innovativeness cannot exist side by side, nations that harbor pirates drive out innovators and slow their own development. In the long term, a policy that abets piracy is a form of national economic masochism.

The clearest short-term losers to piracy, of course, are the developed nations like the United States whose economies have become increasingly dependent on the capacity to innovate. They count on being able to recover the cost of innovation from their customers, wherever located. To the degree that such nations lose customers to a pirate who spends nothing on research and development and can charge accordingly, to that degree is the world's capacity to innovate diminished.

The pharmaceutical industry is one of those especially vulnerable to piracy. Manufacturing costs represent a relatively small proportion of total expenditures; however, on average a new prescription therapy costs $125 million to develop and takes seven to ten years to bring to the market. Along the way, the pioneering company sets standards of quality, safety and effectiveness, then spends millions more informing the worldwide medical community about the medicine's proper use and possible side effects.

In contrast, using proprietary information fully disclosed in the published patent, pirates have only to copy the product, gain regulatory approval in a country where regulatory review is perfunctory, then make and sell the product openly as their own wherever weaknesses in patent laws allow.

Even U.S. patent, trademark and copyright laws and policies, as strong as they are, fall short of protecting American intellectual property from foreign infringement in some ways.

One such shortcoming has been manifest in this country's treatment of process patents. U.S. law prevents the importation, use or sale of foreign *products* that violate U.S. *product* patents, but it has not, until recently, barred entry to products whose manufacture violates U.S. *process* patents. As a result, medicines on which the product patent expired could be manufactured abroad using processes on which U.S. patents were still in effect. The products were then exported to the U.S., where they could be sold cheaply because someone else had borne all the costs not only of inventing and developing the products but of inventing and developing the processes by which they were made. This loophole in patent protection:

- Cost the U.S. thousands of jobs
- Deprived the Federal government of millions of dollars in lost tax revenue
- Reduced funds available for R&D
- Contributed to an unfavorable balance of trade.

"Without question, the American creative genius has been nurtured by a strong legal tradition of protecting the property rights of intellectual property owners."

Representative Bob Kastenmeier (D-WI)

A second weakness in U.S. intellectual property protection may be seen in patent laws covering animal health products. Like human products, these normally undergo Federally mandated testing and review procedures that significantly reduce their effective patent lives. Separate legislation is needed to restore patent life for animal drug products and thus stimulate research to increase the efficiency of food production and, ultimately, the world's food supply.

A third weakness domestically is the uncertainty of patent protection for inventions based on controversial new technologies. It is axiomatic everywhere, not just in the United States, that the more controversial the technology (e.g., genetic engineering) the more uncertain the patent protection. Yet, since protection is a precondition to investment in applied research, the time lag and uncertainties attending the controversy may blunt innovation at its cutting edge.

"R&D is a critical component of the engine that drives our economy . . . . [After World War II,] American scientists and engineers created new products and innovative technologies that led to economic windfalls: robust business expansion, new business development, higher employment, increased exports and sweeping capital expansion. As a result, post-war America became a nation of ideas and opportunity with unprecedented economic growth."

Representative Claudine Schneider (R-RI)

In 1980, the Supreme Court ruled (*Diamond v. Chakrabarty*) that a bacterium altered by recombinant DNA (genetic engineering) to break down oil spills was patentable. That ruling, which applied to unicellular organisms, was extended to multicellular organisms by the Board of Patent Appeals and Interferences of the U.S. Patent Office in its 1985 decision, *Ex Parte Hibberd*. According to that decision, plant cell lines and seeds that have been genetically engineered to produce desired traits are patentable.

On April 7, 1987, the U.S. Commissioner of Patents and Trademarks signed a notice stating that the Patent and Trademark Office (PTO) "now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter." That declaration, which harmonized with the landmark 1980 ruling of the Supreme Court, reversed PTO's previous position that plants and microorganisms could be patented but not multicellular animals.

"America's comparative advantage has always been superior technology — our ability to innovate and invent."

Senator Jay Rockefeller (D-WV)

In a globalized economy, the United States cannot hope to shield its citizens from a new or controversial technology by withholding patent protection. That would only lessen America's ability to compete while inviting its trading partners to develop the same technology and its products for export to the U.S. Although the patent questions surrounding new inventions from biotechnology are often difficult, the governing principles should be those that determine patent law for all inventions. Such a stand ensures an environment favorable to discovery. It also speeds the dissemination of new scientific knowledge since full public disclosure of how the invention was made is a condition for the patent grant.

Finally, it is essential to remember that just as a patent is no guarantee of success, neither does it confer on the patent holder the right to make, use or sell an invention. The granting of a patent in no way diminishes society's control over an invention. All it does is give the owner the right to exclude others from making, using or selling it. Where safety, efficacy and environmental or other public policy concerns are at issue, an invention remains fully subject to laws other than patent law.

"America needs protection — not protectionism — of its ideas and intellectual property. Those very ideas give America its edge; lack of toughness is losing that edge to unethical and actual criminal actions by some of our trading partners."

Senator Dennis DeConcini (D-AZ)

Although shortcomings in U.S. intellectual property laws need to be addressed, few would deny that they are exceptions to the generally strong and sound protection of intellectual property in the United States. By contrast, the problem of overseas piracy remains largely unaddressed.

One way in which patent piracy is costly to U.S. pharmaceutical manufacturers — and ultimately to the American public — is in the unauthorized copying, manufacturing and sale *abroad* of patented products and products made using patented processes. Pirates often infringe both types of patents simultaneously or operate where only partial patent rights or none exist. Because U.S. patents are enforceable only in the U.S., other kinds of sanctions are called for.

The 1984 Trade and Tariff Act empowered the President to apply leverage that could encourage other nations to protect patents (as well as trademarks and copyrights). The Administration now has the authority to withhold trade subsidies or benefits for nations that fail to provide adequate protection for intellectual property and has used this leverage to good effect on several occasions.

We urge continuation of the policy of withholding trade subsidies and benefits from nations that inadequately protect intellectual property. Congress is also urged to adopt provisions for strengthening the nation's ability to deal with patent piracy in all future trade legislation.

We call on the Federal government to exert and sustain intense trade pressure to ensure that U.S. intellectual property objectives are achieved, particularly with Asian and Latin American countries. We also encourage Congress to enforce U.S. patents on manufacturing processes whenever imported products are made overseas by processes patented in the U.S.

However, since infringement of intellectual property rights is a global problem, not just a problem for the United States, unilateral approaches must be evaluated and solutions sought in a global context.

An international framework for intellectual property protection does exist. It consists primarily of multilateral treaties like the Berne Convention, the Paris Convention for Patents, the Universal Copyright Convention and the Madrid Agreement on Trademarks — all administered by the World Intellectual Property Organization. However, this framework is no longer adequate, if it ever was, for the protection of intellectual property.

Although the Berne Convention provides minimal standards for the protection of intellectual property, some of the other treaties do not. The Paris Convention, for example, requires only that its members treat applicants for patents from every other nation as they treat their own; in other words, nations that do not protect intellectual property are as fully in compliance with the Paris Convention as those that do. Additionally, the Convention permits exceptions from patent coverage for a variety of products including foods, medicines and chemicals. Because these treaties were never intended as enforcement mechanisms, they contain no dispute settlement provisions.

Economic integration is daily making the world economy more vulnerable to the strains and distortions caused by inadequate intellectual property protection. The issue has therefore been placed on the agenda of the General Agreement on Tariffs and Trade (GATT), which exists for the purpose of relieving such strains and correcting such distortions.

Intellectual property arrangements negotiated under the GATT could establish adequate *international* standards while encouraging the institution and enforcement of adequate *national* laws. The GATT could accomplish this because it has the power to do what no other world organization can do: tie the protection of intellectual property to trade. Once that connection is made, market access could be used as leverage to ensure universal protection for every international business and every country with intellectual property to protect. And someday, that *will* be literally every country.

The following recommendations deserve consideration because they would help:

- Maintain America's high-technology leadership in human and animal health
- Rectify the nation's unfavorable balance of trade
- Protect the jobs of American workers
- Contribute to fairer, economically beneficial competition in the global marketplace for all nations
- Encourage research that would ultimately benefit people everywhere.

"America's economic edge is its technology and its innovation."

Senator Frank Lautenberg (D-NJ)

SUMMARY OF RECOMMENDATIONS

1 Negotiate through the GATT a broad agreement to eliminate trade and marketplace distortions caused by inadequate protection of all forms of intellectual property everywhere. The agreement should explicitly authorize full use of the GATT trade mechanisms — concessionary and retaliatory — to promote the protection of intellectual property.

2 Complete the anti-counterfeiting code for trademarks that has been before the GATT since the 1970s.

3 Protect innovative manufacturing processes to the same degree as innovative products.

4 Encourage the Federal Administration to use its Congressionally mandated leverage to dissuade other nations from harboring pirates of intellectual property.

5 Resist all efforts to regulate or ban controversial new technologies by denying them patentability.

6 Enact legislation to restore patent life lost to the regulatory review of medical products used to treat animals.

"We need to assure our capacity to develop and produce the cutting edge high-technologies which are at the core of our industrial, economic and military strength. For the next century, it is our research and development infrastructures which will be our most important national security resource, just as the timber to build our naval fleet and the iron ore to cast our cannon were in the last century."

Representative Hamilton Fish (R-NY)

Currently there are no globally uniform standards for patents. A company seeking international protection for its property must file for a patent in each country that is technologically capable of copying its product and manufacturing processes.

Most of the world's major industrialized nations belong to the Paris Convention (PC). According to this agreement, each member must treat the patents of other members exactly as it treats its own.

Most PC members afford some degree of protection to manufacturing processes. Many members, however, do not protect chemical compounds or compositions that have pharmaceutical utility. Here's a sampling of the variety in patent laws:

- The duration of a Japanese patent is 15 years from date of publication, but not to exceed 20 years from the date of filing the application. In 1987, the Japanese Diet enacted a bill to restore patent term life lost during the regulatory review process.
- In Europe the term of protection is 20 years from the filing date.
- Until 1987, South Korean patent law protected manufacturing processes only. In July 1987, the law was amended to include product protection. Both are now protected for 15 years from the date the patent application is published. The measure also tentatively provided retroactive patent protection for products that had been patented but not yet marketed in the United States or South Korea prior to enactment of the bill.
- Indonesia grants no patent protection of any kind.

The Pharmaceutical Manufacturers Association has identified 24 countries that do a poor job of protecting intellectual property rights within their borders:

Argentina, Bangladesh, Brazil, Chile, Colombia, Costa Rica, Ecuador, Egypt, Guatemala, India, Indonesia, Mexico, Pakistan, Peru, Philippines, Portugal, South Korea, Sri Lanka, Taiwan, Thailand, Turkey, Uruguay, Venezuela, Yugoslavia.

In the Trade and Tariff Act of 1984, Congress specified that the President may take retaliatory action against any foreign government that fails to recognize and protect intellectual property rights. Under the law as amended, the Pharmaceutical Manufacturers Association (PMA) has filed complaints seeking to protect pharmaceutical patents in Brazil, South Korea, Thailand and Chile.

Complaints are filed with the Office of the U.S. Trade Representative, which attempts to negotiate settlements. Signed agreements essentially carry the force of law for both the United States and its trading partner.

Under Section 301 of the U.S. Trade Act, PMA protested Brazil's refusal to amend a 1969 patent law that discriminates against pharmaceuticals. By denying patent protection to pharmaceuticals, Brazil gives sanctuary to pirates who make patented drugs without paying the patent owner for the right to do so.

The complaint against Thailand was filed under Sections 501 and 502 of the Trade and Tariff Act of 1984, citing the lack of patent protection. In Thailand, domestic pharmaceutical companies, which pirate U.S. medicines but do no research of their own, control 57% of the market.

Also under Section 301, the U.S. protested Chile's refusal to amend its Industrial Patent Law, which expressly denies patent protection to pharmaceutical products. In 1986, Chilean companies held 86% of the market for pharmaceutical products discovered and developed by PMA members and patented in the U.S. American companies held 14%.

The difficulties of bringing about change through purely bilateral negotiations are illustrated by a complaint brought against South Korea under Section 301 and apparently resolved in July 1986. At the time, in what was considered a precedent-setting case, Korea signed an agreement to protect:

- U.S. pharmaceuticals and chemical products
- Computer software
- Specified products in U.S. research pipelines.

By March 1988, it was clear that South Korea had failed to live up to its agreement. In a letter to U.S. Trade Representative Clayton Yeutter, PMA President Gerald Mossinghoff charged that since signing the bilateral agreement, the South Korean government had done nothing but try to renegotiate it in order to "reserve the right to copy new pharmaceutical inventions and further deny fair market access for American products."

PIRACY: HOW GREAT A TOLL?

The International Trade Commission (ITC), which has studied the effects of patent, copyright and trademark infringement, estimated losses to the U.S. economy in 1986 at $43-$61 billion, up from an estimated $6-$8 billion in 1982.

The ITC survey included data from 10 pharmaceutical firms whose aggregate losses amounted to nearly $2 billion. A conservative projection for the entire industry might be three times that figure, or $6 billion. In an industry that reinvests 12-15% of its U.S. sales in research and development, that could mean a reduction in R&D funding of between $720 and $900 million.

Financial losses do not tell the whole story. Lost sales reflect lost markets, and markets once lost are very difficult, if not impossible, to recover. In turn, lost markets mean lost jobs. By discounting the costs of research and development, piracy distorts international trade in ways that ultimately work to everyone's disadvantage.

Controversy surrounding the regulation of food and drugs in a democracy is inevitable. Instead of blaming the Food and Drug Administration and each other when something goes wrong, critics should work together to provide the Agency with the resources it must have to carry out its responsibilities.

What we must seek is a proper balance — a process that fully ensures the safety of drugs, but without unnecessary delays or over-regulation. We want a process that truly promotes the public health, not only by keeping unsafe and ineffective drugs off the market, but also by enabling beneficial new drugs to reach those who need them faster.

Richard Schweiker
Secretary, U.S. Department of Health & Human Services, 1981-1983

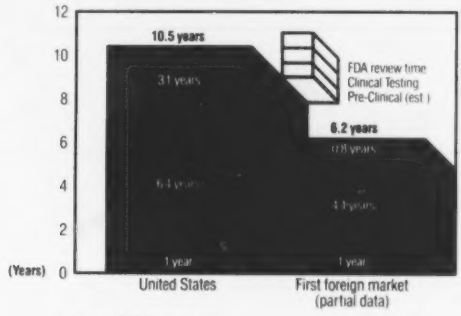
Drug safety is a broader issue than is commonly assumed. It involves more than weighing the benefits of pharmaceutical innovation against its risks. Few pharmaceutical innovations are more hazardous to health, for example, than the one that could save a life but is not yet available. And the availability lag between the U.S. and other nations with rigorous review procedures continues to raise citizen concerns about the treatment of patients in this country.

Disease not only kills people and makes their lives miserable. Figures provided by the Health Care Financing Administration and the National Center for Health Statistics show that disease drains the U.S. economy of more than $350 billion a year, not including lost productivity.

Streamlining regulatory procedures to achieve even small reductions — either in the time it takes to develop a new drug or the time it takes to review a New Drug Application (NDA), or both — would pay human and economic dividends out of all proportion to cost.

Critics usually blame the FDA for the delays that endanger public health. Indeed, as everyone at the Agency continues to acknowledge, the review process could be further streamlined without compromising safety.

DRUG DEVELOPMENT TIMES IN U.S. AND ABROAD



Source: PMA Annual Survey

On average, it takes longer to test and review (develop) a medicine in the U.S. than it does abroad. The chart compares average U.S. and overseas development times for 15 medicines approved in the U.S. in 1986 but previously approved abroad. The average review time abroad was less than a year compared with more than three years in the U.S. "Pre-Clinical test" refers to the estimated average time for tests to show safety in laboratory animals. The category does not include the average time required to discover and profile a new medical molecule.

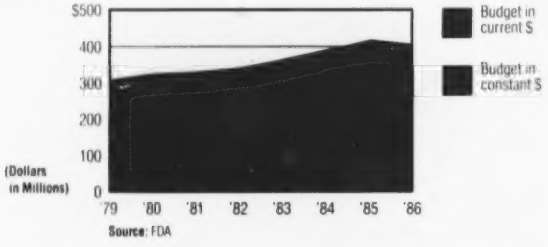
But if safety is not a simple concept, neither is regulatory delay. True, less-than-optimal organization and management at FDA can retard the review process. But so can:

- The failure of industry to submit adequate information to FDA in a usable and timely manner
- The failure of government to provide FDA with resources adequate to its responsibilities.

Experts inside and outside of government have been heaping criticism on the management of FDA for decades. The time has come, we believe, to focus attention also on other important factors that affect regulatory dispatch.

The Information Factor: The FDA maintains that New Drug Applications (NDAs) it judges to be complete and thorough upon initial submission are approved in an average of 13.5 months. Those less well prepared take an average of 28 months — more than twice as long. Clinical (human) trials represent the phase of testing on which approval for marketing ultimately hinges, and to ensure that they will, in fact, generate the data FDA considers essential to an informed decision, sponsoring companies are encouraged to consult with the Agency beforehand. Yet fewer than 40% actually do.

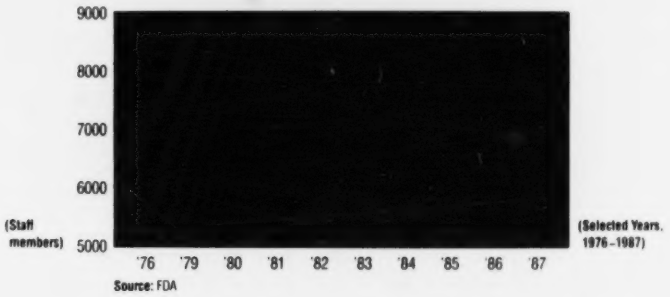
FDA ADMINISTRATION BUDGETS, 1979–1986



Source: FDA

The Resource Factor: In the period 1978-1982, the number of NDAs increased 75%, while the number of FDA reviewers decreased by 8.5%. Between 1978 and 1986, FDA's budget, adjusted for inflation, fell 12%. The reductions hurt not only staff morale, recruitment and retention, but management of the drug approval process.

FDA PERSONNEL TOTALS



Source: FDA

Regulatory rigor at FDA keeps biomedical research and pharmaceutical industry performance up to the highest mark, assuring patients, physicians and the public alike that medicines will be as safe and effective as science can make them. But FDA can hardly be expected to combine rigor with dispatch when:

- Staffing and funding are insufficient for carrying out mandated responsibilities
- Salaries and working conditions fail to match the qualifications of the scientists, physicians and managers working at FDA
- Information processing systems are less than state-of-the-art
- Continuity of leadership is lacking.

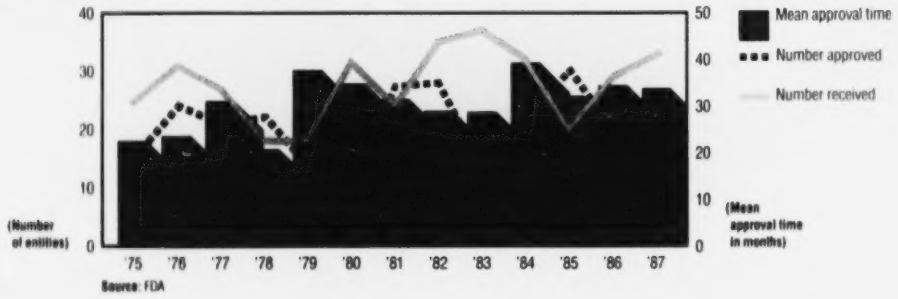
Failure to provide these essentials may result in part from the inability of the public and its policymakers to accept what cannot be changed.

One such inevitability, though rare, always unsettles nonscientists. And that is disagreement among scientists over what constitutes sufficient grounds for FDA approval. The fact that FDA reviewers agree with their scientific advisors 90% of the time never makes the news. Their occasional disagreements, on the other hand, make shocked headlines, when they usually should be seen as welcome signs of evolution in the midst of essential stability. Another unchangeable reality is the complexity of the interaction between industry and Agency and the implications of that complexity for public policy.

There is a widespread assumption that the rigor of FDA's review process acts as a brake on pharmaceutical innovation. People unacquainted with risk-benefit ratios and other constructs for evaluating new medicines fall easily into the simplistic notion that the Agency's two imperatives — safety and efficacy on the one hand, innovation on the other — exist in a simple state of counterbalance, like opposite ends of a teeter-totter.

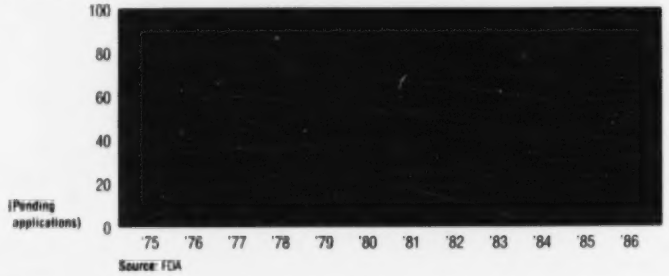
In fact, safety and efficacy do not conflict with rapid innovation, since — as the industry is exquisitely aware — any pharmaceutical innovation that is less than safe and effective will prove unprofitable and possibly even disastrous to its sponsor. The danger to innovation, we believe, arises less from overzealous efforts to ensure safety and efficacy than from failure to provide FDA with the data and resources it needs to perform efficiently.

FDA REVIEW TIMES FOR NEW MOLECULAR ENTITIES



Currently, FDA's NDA review and approval processes take between two and three years. Given adequate resources, FDA staff members believe they can reduce the time to less than one year, and they set themselves that goal in "A Plan For Action," published in July 1985. Although two years of effort failed to shorten average review time significantly, enough progress was made to warrant publication of "A Plan For Action, Phase II" in May 1987. NDAs were prioritized as to therapeutic value, and some of the medically more important ones were being cleared in under a year. *(See sidebar: "Three NME-NDAs . . .")*

NEW MOLECULAR ENTITY BACKLOG



Commissioner Frank Young earned wide recognition for building intra-Agency consensus for targeted improvements at FDA. No less importantly, his years in office represent a continuity of leadership and direction long denied the Agency. (Seven commissioners or acting commissioners sat in his chair in the seven years prior to his arrival in 1984. By the end of 1987, he had served longer in the position than anyone in the previous 20 years.)

Much remains to be accomplished:

- Additional review divisions must be created and staffed to match the explosion of knowledge and diversification of activity in biomedical research. We applaud the establishment of the new Divisions of Gastrointestinal and Coagulation Drug Products and of Antiviral Drug Products as evidence of FDA adaptability to the forces of change, and we urge Congress to supplement the Agency's budget accordingly.

Source: PMA

- Use of state-of-the-art computer networks must be encouraged so that FDA scientists may more readily exchange and analyze information with the Agency's far-flung research centers and with key outside sources of information.
- FDA also plans to provide companies with written suggestions for improving their performance as applicants and periodic status reports detailing the progress of the various facets of each NDA — pharmacology, statistics, clinical data — within the complicated review process. Agency-industry interaction of this kind could well become a major stimulant to pharmaceutical innovation in the U.S.

To meet its goals, the Agency must have the requisite resources, both human and material, including additional funding. Granted, the government must restrain Federal spending. But it cannot do so by abandoning priorities. On the contrary, the greater the constraints, the greater the obligation to prioritize.

Because nothing is more basic to the success of a society, public health and the agencies that safeguard it must receive a high priority. Specifically, the long-term constant-dollar decline in FDA's budget must be reversed. The taxpayers' current annual bill for FDA — $2 per person per year for overseeing the entry and retention in the marketplace of food and health products amounting to fully one-fourth of the $4.2 trillion U.S. economy — is hardly excessive and need be raised by only a few cents to achieve a significant payback in both human and economic terms.

Since everyone is vitally interested in the wholesomeness of food and the safety and efficacy of medicines, the regulation of food and drugs can never be conducted in a democratic society without intense public scrutiny. Americans expect FDA not only to regulate food and drugs but to deal with the scrutiny that inevitably attends regulation.

Dealing with scrutiny and the controversy it provokes consumes a great deal of executive and staff time. Recently, top FDA officials have been testifying at an average of about 40 hearings a year. This demand on Agency resources must be factored in realistically at budget time.

Let us close ranks in the national interest and empower FDA to do all that we ask of it.

SUMMARY OF RECOMMENDATIONS

1 Substantially increase Federal funding for FDA now.

2 Impose no added responsibility on the Agency without commensurate increases in its budget.

3 Support proposals to make careers with the Agency more attractive to top-drawer physicians and research scientists. *(See sidebar: "FDA Staff — Attracting and Retaining the Best.")*

THREE NME-NDAs* THAT WERE APPROVED IN LESS THAN A YEAR IN 1987

Iopidine (apolonidine hydrochloride) for lowering eye pressure after laser surgery	Alcon	3 months
Retrovir (AZT) for treating human immunodeficiency virus (HIV)	Burroughs-Wellcome	4 months
Mevacor (lovastatin) for lowering cholesterol	Merck	9 months

**NME: New Molecular Entity (formerly NCE: New Chemical Entity)*
NDA: New Drug Application

Two conditions must be met if the Agency is to reach and sustain the level of performance it has set for itself. The first is adequate funding. The second, closely related to the first, is an enhanced ability to attract and hold top-drawer scientific and managerial talent. But that involves more than pay scales and working conditions. Thus Merck endorses and supports the vision that sees the Agency expanding its role to become a scholarly center for the study of the sciences, methods and systems that play key roles in the regulatory review process. To this end Commissioner Young has advanced proposals to:

- Relocate FDA from Rockville to the Bethesda, Md., campus of the National Institutes of Health. This move would open possibilities for staff cross-fertilization, including teaching opportunities and close contact with postdoctoral students and emergent technologies at NIH.
- Establish, in cooperation with nearby research universities (e.g., Johns Hopkins, George Washington, University of Maryland), extramural academic programs leading to post-graduate degrees in regulatory medicine.
- Institute a sabbatical program comparable to those offered in academia.
- Strengthen and emphasize FDA programs of research, especially in areas such as the methods and validation of biomedical research, clinical trial design and *in vitro* testing.
- Enable the Agency to assert itself as a major voice in health and health research. FDA should be recognized as a *source* of analysis and advice for government, industry and academia.

Helping the Agency do more to attract and hold top-drawer scientists will ultimately make its review process more efficient.

Centuries-old doctrines, originally adopted to impose liability on wrongdoers, today impose liability on those who have done no wrong. In the pharmaceutical industry, the consequent product liability crisis diverts resources from biomedical research, discourages research in medical fields vulnerable to litigation and threatens to limit the availability of medicines and vaccines vital to public health.

Across the board, the message [that tort litigation is sending] to scientists, engineers, doctors and pharmacologists is this: Don't innovate, don't experiment, don't be venturesome, don't go out on a limb. A legal system that persistently sends such a message to the technological community . . . . is sowing the seeds for national disintegration.

Peter Huber
Senior Fellow, Manhattan Institute for Policy Research

The product liability crisis presents a startling example of a failure in public policy that has shrunk industry resources for research, threatened the availability of vitally important vaccines and discouraged industry research on new medicines likely to be targets of litigation. A consensus among leaders of public opinion and makers of public policy recognizes that reform of U.S. tort law is long overdue.

Over the past two decades U.S. tort law has undergone a sea change. For most of the nation's history, a manufacturer was held liable only upon proof that it was negligent and that its negligence had caused injury. During the 1960s, however, courts developed a doctrine of strict liability, holding manufacturers responsible if a product was defective in some way.

In the 1980s some courts have gone still further, declaring the manufacturer responsible even when the risk at the time of manufacture was unknown or even unknowable. An example is a 1982 New Jersey decision in which the court held a manufacturer liable for failure to warn of risks when no evidence existed that those risks were known at the time the product was manufactured.

The cost to the public in litigation fees, delay in research projects and deletion of good products from the market has been incalculable.

Despite the shift from a fault-based system to one of strict liability, the rules governing damage awards remained unchanged. A set of doctrines adopted for imposing liability on wrongdoers now may be used to impose liability on those who have done nothing wrong, either deliberately or negligently.

There are some who would like to see tort law function as a form of social insurance for the ill or injured. The social insurance application of tort law meshes with the doctrine of joint and several liability to ensure that the plaintiff will receive the full amount of the jury award. (Parties to a liability action may be sued separately or together at the plaintiff's option. Thus, whenever there are joint defendants in a tort case and some cannot pay their share of the judgment, the others must assume that share along with their own. A defendant who is only 1% at fault may be held 100% liable and required to pay all of the damages.)

Despite these efforts to make sure that victims are fully compensated, the amount of the award is substantially reduced by litigation costs. According to a 1985 RAND Corporation survey, plaintiffs received only 46% of the full amount of the jury award for their injuries. Approximately 866,000 tort lawsuits were settled in state and Federal courts that year, resulting in awards totalling between $29 and $36 billion. With 37% of this amount going to legal expenses for both sides, 15% to litigation time and claims processing, and another 2% to court costs, plaintiffs received *less than half* the award granted.

Some companies find it difficult to purchase liability insurance. What commercial insurance is made available today usually comes with very high deductibles of $15-$20 million. It also excludes coverage for certain "too risky" products such as any AIDS therapy, even when such a therapy has yet to reach the market and is still undergoing clinical (human) trials on volunteers whose medical expenses the company has agreed to pay.

Insurance in anticipation of unreasonable awards by juries is a less-than-satisfactory solution, if only because it diverts funds that could otherwise be invested in research and development.

Many companies contend that the excesses and unfairness of the system that have caused liability insurance to become either prohibitively expensive or unavailable are having dangerously adverse consequences for public health.

In 1981, 13 companies were producing vaccines for five serious childhood diseases. Today, because of liability costs, only three companies — Merck, Lederle and Connaught — are producers of the mandatory childhood vaccines. For a time in 1984-85, Connaught also dropped out because its underwriter refused insurance for DPT (diphtheria-pertussis-tetanus) vaccine, causing, however briefly, the nation's first childhood vaccine shortage.

The high cost or unavailability of liability insurance has also profoundly discouraged research in certain medical fields, most notably obstetrics and gynecology. Industry research in this area has declined dramatically. This is also the only major field of medicine in which the National Institutes of Health is conspicuous by its absence.

Trial lawyers and consumer groups blame the insurance industry for the crisis. Insurance companies, they say, competed for dollars when interest rates were high and then, when the rates fell and their reserves could not cover claims, doubled and tripled their premiums to meet the deficits.

Insurance companies blame trial lawyers for encouraging the public to sue for even the most frivolous reasons. Insurers also blame juries that go far beyond compensating plaintiffs for lost wages, medical payments and other measurable losses, to award excessive amounts for unquantifiable non-economic losses such as "pain and suffering" and "emotional distress." Juries are also faulted for awarding punitive damages disproportionate to the degree of fault.

No one, however, seriously doubts that a liability crisis exists. When the failure of public policy threatens the availability — and even the development — of essential medical products or services and diverts enormous sums from research and other productive uses into insurance premiums and other defensive practices, it is long past time for action. Fair and effective Federal legislation is needed now to harmonize tort law at the state level and help resolve the liability crisis.

1 Establish a clear fault-based standard of liability.

2 Presume the safety of products cleared by the FDA for marketing, unless fraud or deliberate withholding of pertinent data was involved in obtaining clearance.

3 Establish a defense against punitive damages for drugs and medical devices that received approval from the FDA before marketing, unless there is an intentional or wrongful withholding or misrepresentation of information required to be submitted to the FDA.

4 Reserve punitive damages for cases in which a defendant has displayed conscious and flagrant indifference to the safety of others.

5 Limit amounts that can be awarded for punitive damages. Require punitive damages to be set by a judge in separate proceedings after compensatory damages have been awarded.

6 Limit non-economic damages. Uncertainty about what damages should be awarded for "emotional distress" and "pain and suffering" makes the sky the limit and has an impact on the affordability of insurance. Federal law should guide juries by establishing limits on the amounts that can be awarded as non-economic damages.

7 Nullify "joint and several liability" in the absence of concert of action and apportion damages on the basis of comparative fault.

8 Recognize collateral sources of compensation so that juries can be alerted to the fact that the plaintiff has recovered money, or may recover money, from more than one source for the same injury.

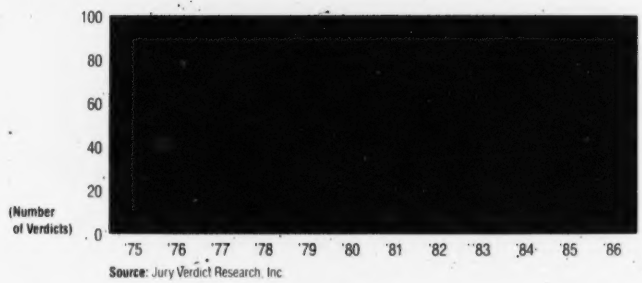
9 Set guidelines for expert testimony. Prevent lawsuits from being decided on the basis of which party can afford to hire the most experts by admitting testimony only from those who are truly qualified and whose testimony is corroborated by objective evidence, such as a scientific study, consistent with generally accepted scientific principles.

10 Require large damage payments to be made in installments.

"We must demonstrate to young people — especially to the brightest of them — that the rewards for careers in science and engineering are really there. That requires a thriving manufacturing industry, actively challenging technological frontiers."

Erich Bloch
Director, National Science Foundation

MILLION-DOLLAR JURY VERDICTS FOR PRODUCT LIABILITY



Source: Jury Verdict Research, Inc.

WHAT THE STATES ARE DOING

Jury awards for product liability have risen steadily in amount since 1980. The average payment topped the million dollar mark in 1986, and the trend continues.

Among the groups working to curb the trend is the American Tort Reform Association (ATRA), which encourages the abolition of:

- Joint and several liability (defendant may be required to pay according to ability to pay, not degree of liability)
- Collateral source rules (information about the plaintiff's ability to recover from more than one source is withheld from the court)
- Prejudgment interest (defendant pays interest on the jury award retroactively from the time the suit was filed).

ATRA also supports limits on punitive damages and non-economic damages (distress, embarrassment, etc.) and penalties for frivolous claims.

Although only two states have abolished joint and several liability, 29 have limited its impact. Six have repealed collateral source rules, making it mandatory to offset awards by amounts received from collateral sources. Eleven allow offsets or information as admissible evidence.

Tort reform seems to be the way of the future. By 1988, 37 states had already instituted, and 31 were actively working toward, reforms.

Punitive Ceiling

Alabama	$250,000
Colorado	Equal to compensatory award
Florida	Three times compensatory award
Georgia	$250,000
Kansas	Defendant's highest 5-year income or $5,000,000
Missouri	Separate trial to decide punitive award
New Hampshire	Punitive awards prohibited
New Jersey	Separate trial to decide punitive award
Oklahoma	Not to exceed compensatory award
Texas	Four times compensatory award or $200,000
Virginia	$350,000

Joint and Several Liability Abolished

Utah, Wyoming

Several Liability Only (Joint Abolished)

Alabama, Indiana, Kansas, Kentucky, Oklahoma

Joint and Several Liability Limited

Alaska, Arizona, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Louisiana, Michigan, Minnesota, Missouri, Montana, Nevada, New Jersey, New Mexico, New York, North Dakota, Ohio, Oregon, South Dakota, Texas, Washington

Collateral Source Rule Modified

Alaska, Colorado, Connecticut, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Michigan, Minnesota, Missouri, Oregon

Collateral Source Rule Abolished

Florida, Montana, New Jersey, New York, North Dakota, Ohio

Non-economic Ceiling

Alaska	$500,000	(except physical impairment/disfigurement)
Colorado	$250,000 - $500,000	
Hawaii	$375,000	(physical pain and suffering)
Idaho	$400,000	(amount adjusted for annual wage increase)
Kansas	$250,000	(pain and suffering)
Maryland	$350,000	
Minnesota	$400,000	(consortium loss, emotional distress, embarrassment)
New Hampshire	$875,000	
Oregon	$500,000	(non-economic)
Washington	$177,000 - $493,000	(formula)

Penalty For Frivolous Claims

Alabama	Penalty permitted
California	Certificate of merit required
Colorado	Codified Rule 11 (Certification of Merit)
Connecticut	Twice costs and attorney fees
Georgia	Costs and attorney fees
Hawaii	25% of original claim
Idaho	Fees, costs, expenses required
Illinois	Penalties permitted
Indiana	Costs and fees
Iowa	Penalty permitted
Michigan	Penalty permitted
Minnesota	Costs and fees
New Hampshire	Penalty permitted
New York	Costs and fees penalty to $10,000
Ohio	Costs and fees
Oklahoma	Codified Rule 11 (Certification of Merit)
Oregon	Fees, costs, expenses required
Rhode Island	Penalty permitted
Texas	Penalty permitted
Virginia	Penalty permitted
Wyoming	Penalty permitted

Prejudgment Interest Limited

Iowa, Louisiana, Michigan, Minnesota, Nebraska, Oklahoma, Rhode Island, Texas

Merck applauds the efforts of these states to enact tort reform. Nevertheless, we believe that a Federal law establishing nationwide uniformity would best serve the public interest.

Until recently, the United States has led the world in technological innovation, in part because of a strong partnership between government, academia and industry. Many economists believe that economic growth is built on a foundation of innovation, which in turn depends on advances in fundamental science. But neither innovation nor basic research is being encouraged and supported at the level necessary to maintain the nation's competitive position.

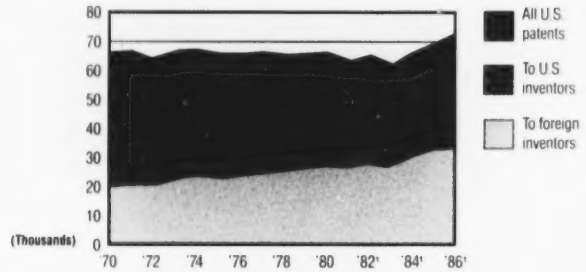
What role should the U.S. government play with respect to R&D? That role is not to manage technology-based commercial innovation but to create the conditions for such innovation. The government should provide an encouraging and supportive environment and infrastructure within which industries select and develop commercial technology . . . .

The most important role for government in creating the conditions for commercial innovation is to support universities in their efforts to generate research and provide manpower . . . . Industry will never be able to meet more than a small fraction of university R&D funding needs . . . . The primary responsibility for ensuring a strong, healthy academic research system and thereby for providing an adequate supply of research and skilled people must rest with the Federal government.

Roland W. Schmitt
Chairman of the National Science Board of the National Science Foundation; President, Rensselaer Polytechnic Institute; formerly Senior Vice President and Chief Scientist, General Electric Company

America's achievements in technological innovation over the years have arisen from a strong, vital research establishment, nurtured by government, academia and industry. This synergistic relationship has produced such fundamental breakthroughs as the transistor, the laser and recombinant DNA technology (genetic engineering). United States research laboratories hold an enviable record of Nobel prizes, scientific journal citations and patents, all of which are barometers of scientific achievement.

U.S. PATENTS GRANTED, BY NATIONALITY OF INVENTOR AND DATE OF APPLICATION



*Estimates

Source: Science & Engineering Indicators–1987

Other nations, realizing that a stronger base in science and technology will give them an edge in fiercely competitive international markets, are according research a high national priority — allocating funding, establishing incentives for research, training the talent pool necessary to conduct research and commercialize technology, removing barriers to technological development and coordinating the efforts of all sectors to achieve economic growth.

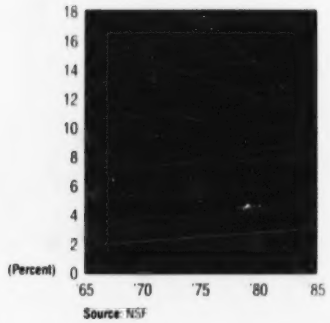
Basic research, the foundation of new knowledge upon which technological innovation builds, is receiving particular attention. For example, over the past decade, West Germany has doubled spending on basic research — now 22% of its R&D budget, nearly twice the 12.2% the U.S. invests. Japan's outlay has tripled, with approximately 13% of R&D going for basic research. *(See sidebar: "The Growing Japanese Stake . . .")*

Everyone benefits from a worldwide increase in fundamental knowledge, freely accessible to all nations. The best minds of every nation are needed to help solve the problems of famine, poverty and disease that plague the world. It is clear, however, that nations fostering substantial basic research programs are more likely to produce the innovative technologies that lead to their own economic growth. The corollary should also be apparent: a decline in basic research can slow the rate of innovation and thus the rate of growth.

Other nations are rivalling traditional U.S. ascendance in science and technology. In 1986, for example, the number of patents issued to foreign inventors by the U.S. patent office amounted to nearly half the total. A recent study suggests that Japanese-held patents reflect a higher degree of innovativeness than those granted to American inventors, and that this pattern may have prevailed since 1976.

U.S. investment in civilian R&D has been shifting from applied to basic research since 1980 — from 26% to an estimated 39% in 1987. While increased recognition of the importance of basic research is essential, it must not be at the expense of applied. Both are necessary for continuing innovation.

BASIC RESEARCH AS A PERCENT
OF TOTAL FEDERAL R&D



Despite this rise, the percentage of total Federal R&D investment devoted to basic research has actually decreased in recent years. This decline can be attributed to the dramatic rise in the percentage of all Federal research allocated to military R&D, which contributes only minimally to basic research. The percentage has jumped from 48% in 1980 to approximately 67%.

In contrast, U.S. government support of basic research in universities has declined as a portion of Federal R&D spending. Only about 20% of total Federal civilian R&D funding is currently devoted to basic research in academia. While this kind of research might not produce new weapons systems, it is equally, if not more, essential to national survival. With so many competing budget priorities, each worthy of consideration in its own right, and overlapping regulations, each directed toward a particular and socially useful goal, it is more imperative than ever for decision makers in Congress and the Administration to develop a clearly articulated public policy in support of innovation.

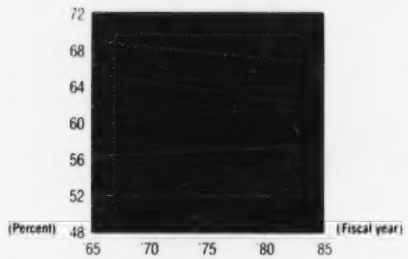
One way to achieve a more coordinated policy is to strengthen the synergistic partnership between government, academia and industry that has made American innovation and technological progress so successful. Although the divisions between the partners are far from rigid and their activities frequently overlap — indeed, that is one of the key advantages of an open, entrepreneurial economy — government and academia have traditionally been responsible for basic research and industry for applied.

The partnership has been a balanced one, each partner dependent on the others fulfilling their special responsibilities. The following functions, while not exclusively so, are primarily the province of the Federal government:

- Funding and encouraging basic research
- Accelerating the transfer of technology to the marketplace
- Expanding the nation's talent base in science and technology.

In this chapter, we will address the need for sustained support for basic biomedical research in the nation's universities and at the National Institutes of Health (NIH) through Federal funding of NIH. We will also examine the transfer of technology

MILITARY R&D AS A PROPORTION
OF ALL FEDERAL R&D



Source: Office of Management and Budget
Special Analysis k 1985

from laboratory to marketplace. In the next chapter, we explore the current state of U.S. education and what must be done to produce the next generation of scientists, engineers, managers and other members of a technological work force.

NIH: KEYSTONE OF THE ARCH

In the NIH, which celebrated its centennial in 1987, the Federal government has created and sustained the world's foremost center and financial resource for basic biomedical research as well as a major center for clinical and epidemiological research. From the discovery of a cure for pellagra in 1914 to today's projects aimed at cancer and AIDS, the NIH has been in the vanguard of biomedical science. *(See sidebar: "NIH: World Leadership . . .")*

NIH allocates more than 80% of its budget to basic research at universities, reserving the balance for its own endeavors. A major strong point of NIH has been the ability to fund relatively long-term research projects in comparison to academic research funded by other agencies or private sources, which often require grant seekers to reapply every two years. This stability and continuity, a prerequisite for basic research, must not be jeopardized by cutbacks in funding.

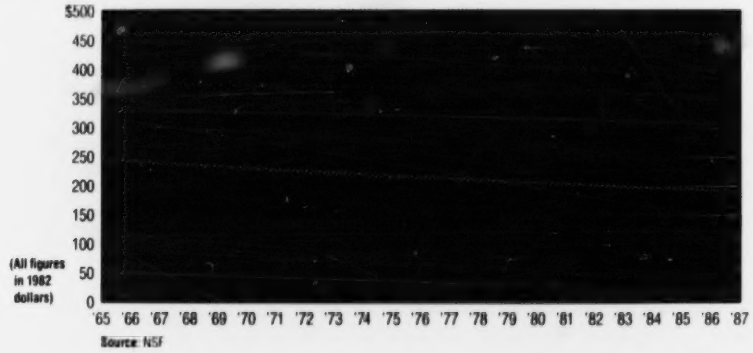
Difficult though the choices are, cutbacks in biomedical research funding are shortsighted at best. Although an econometric study by the Congressional Office of Technology Assessment (OTA) concluded that traditional return-on-investment calculations could not fairly be applied to basic science — partly because the objectives include the "public good," which cannot, by its nature, be quantified, and partly because the relationship is long-term, indirect and subject to many other economic factors — leading economists generally agree on the validity of linking research and productivity. There is agreement, too, that the return to society is far greater than the private return.

Uncertain as these calculations may be, consideration of what NIH has achieved in the century since its founding is evidence enough of the value of research.

THE ROLE OF THE UNIVERSITY

Uncovering fundamental knowledge is traditionally the task of the university, and American universities are among the best in the world. Students from every

FEDERAL OBLIGATIONS FOR R&D PLANT TO UNIVERSITIES AND COLLEGES, FISCAL YEARS 1965 – 1988 (EST.)



country stream to U.S. campuses for advanced training in many fields, especially the sciences, and more than 60% stay on to become U.S. residents and citizens following graduation.

America's institutions of higher learning — the heart and soul of the nation's research establishment — are currently encountering serious difficulties on two fronts. The first is in funding and encouragement for research — not only in dollars, but also in tax incentives and in the stability and predictability of funding necessary for long-term projects. The second area is infrastructure, the facilities and instrumentation essential to teaching and conducting research.

Industry is helping to fill the vacuum in many important ways that can shorten the path from laboratory to marketplace. The National Science Foundation (NSF) estimates that corporations spent $670 million on university research (both basic and applied) in 1987 — approximately 8% of all university research — and that within five years the proportion will grow to 10% or 12%. In the area of manufacturing technology, particularly, research advances would help raise national productivity to more competitive levels. Although academic researchers can productively devote a portion of their efforts to applied research, universities must remain the locus for basic research. Without this foundation, applied research would simply dry up — or move elsewhere.

In order to carry out this mandate effectively, universities need a major infusion of money for their physical plant and equipment as well as tax and other incentives to encourage new construction and equipment purchase.

The university facilities where most U.S. basic biomedical research is performed are all too often antiquated and the equipment obsolete. NSF surveys of science and technical fields reveal that less than 20% of laboratory instrumentation may be state-of-the-art, while half may be inadequate for research purposes. A Midwestern university could not accept a quarter-million dollar grant for genetics research because of lack of laboratory space. Such deficiencies are compounded by the sophisticated (and expensive) computers, instruments and specialized environments required for research in this high-tech age.

These problems result from the drop in Federal support for university research infrastructure that marked the 1970's. Direct Federal support of R&D physical plant in universities plummeted from $469 million (in 1982 constant dollars) in 1966 to

$40 million in 1981. In 1966, NIH allocated 11.7% of its research grants to instrumentation. By 1982, that proportion had dropped to 4.5%. Research budgets were so sparse that even the funds allocated for facilities and equipment were cannibalized "temporarily" for programs.

Funding for university research infrastructure began to rise once again in the mid-1980's, but a great deal of damage had already been done. The White House Science Council Report estimates it will take $10 billion over the next decade, with at least half this amount from Federal funds, to solve the problem.

Congress has recognized the needs in H.R. 1905, The University Research Facilities Revitalization Act of 1987:

> The Nation's capacity to conduct high quality research and education programs and to maintain its competitive position at the forefront of modern science, engineering, and technology is threatened by [a] research capital deficit, which poses serious and adverse consequences to our future national security, health, welfare, and ability to compete in the international marketplace.

It is essential that policymakers continue to fund institutions where the research is of the highest quality as well as encourage the expansion of this country's seriously depleted scientific talent base by funding developing research centers.

THE ROLE OF INDUSTRY

The pharmaceutical industry, which supplies nearly half the funding for U.S. biomedical research, both basic and applied, has become increasingly involved in basic research. This is partly because Federal funding has not proved sufficient and partly because this direct involvement is essential in reducing the development time from a promising idea to a new medicine or therapy.

Moreover, the dramatic gains in new knowledge over the past two decades have blurred traditional demarcations between "basic" and "applied" research. Vaccine development, for example, is closely intertwined with efforts to increase fundamental understanding of the immune system.

Merck is no exception to this trend. Nevertheless, the prime responsibility for basic research must continue to rest with NIH and the universities. The potency of these synergistic relationships is dramatically illustrated by two new Merck products. The success of 'Mevacor,' Merck's new product for lowering cholesterol, will be enhanced by NIH studies that established a causal link between cholesterol and coronary artery disease. The development of 'Recombivax,' Merck's recombinant vaccine for hepatitis B, depended, in part, on NIH-funded basic research at universities in genetic engineering and on Merck-funded applied research at universities into recombinant production in yeast of the vaccine's key antigen. *(See sidebars: "Mevacor" and ". . . Merck and the University.")*

While industry's involvement in basic research contributes greatly to synergy between the partners, this investment still does not — and should not — exceed more than a small percentage of the total.

The reason is clear. While the knowledge that flows from basic research is essential to innovation and must be paid for, it does not result directly in products that can be patented and sold.

"Research, by its nature, requires nurturing. It is a time- consuming process because it explores the unknown and moves cautiously to ensure the public's safety . . . . But the pace of research cannot be forced or hastened . . . . Success in any one instance is uncertain, yet overall progress is virtually guaranteed. Even more certain is the fact that there remain diseases and health problems to conquer. The partnership between government, academia and industry is the best guarantee that this vast research enterprise will continue to prosper. The NIH recognizes that 'the partnership' is a national treasure that must be guarded well."

James B. Wyngaarden, M.D.
Director, National Institutes of Health

Industry's primary role in the biomedical research partnership is the discovery and development of new medicines and other medical products through applied research. This is the research that has not only led to the discovery of more than 90% of the new medicines introduced in America since World War II but continues, through sales of these medicines, to generate half or more of all the funds available for biomedical research today.

STRENGTHENING THE PARTNERSHIP

I believe a vigorous science and technology enterprise involving the private sector is essential to our economic and national security as we approach the 21st century . . . . It is important not only to ensure that we maintain American preeminence in generating new knowledge and know-how in advanced technologies, but also that we encourage the swiftest possible transfer of federally developed science and technology to the private sector . . . [in order] to keep the United States on the leading edge of international competition.

President Ronald Reagan
Executive Order - "Facilitating Access to Science and Technology" - April 1987

In the course of accomplishing their specific missions, the nation's 400 Federal laboratories generate considerable information of potential commercial value. The challenge has always been how to make this information available in ways that promote economic growth while still protecting the public interest. But without some provision for patent rights, businesses did not have much interest in using this information. After all, except for classified material, laboratories made all their findings public, giving competitors full access. Moreover, there were few precedents and no structures for interaction between the laboratories and the private sector. Industry feared government red tape; government officials were uncomfortable

with the commercial application of publicly funded research. None of these objections deterred foreign companies, however. Accustomed to dealing with governments, they used the information to develop products that were later sold back to the U.S.

As a result, in 1986 Congress passed the Technology Transfer Act. Designed to provide the missing incentives for government-industry cooperation, the Act authorizes NIH and other Federal laboratories to negotiate agreements, including patent rights, directly with companies and other outside groups, without cumbersome agency review. As an incentive to government researchers, the law entitles the inventors to at least 15% of the royalties the laboratory receives, up to a maximum of $100,000 per person.

The impact of the 1986 Act and its predecessors — the Bayh-Dole amendments to the Patent Act of 1980 and the Stevenson-Wydler Technology Innovation Act of that same year — has been limited. Argonne National Laboratory is cooperating with the steel industry to develop new technologies, and the Automated Manufacturing Research Facility established by the National Bureau of Standards has provided a test center for innovation in manufacturing for some time. But examples are rare, and few actual agreements have been concluded between companies and laboratories.

Despite the stated priority on moving scientific ideas from the laboratory to the marketplace as quickly as possible, and despite the mechanisms that have been put in place by laws, regulations and executive orders, the Act is not being effectively implemented. For example, when the Solar Energy Research Institute (SERI) suffered a budget cutback, one of the first casualties was the industrial applications program.

Under the present law, technology transfer is not a priority for the busy administrator of a U.S. Federal laboratory, but an add-on responsibility. Nor is there an established set of procedures, or any coordinating agency whose primary mission is technology transfer. Many questions regarding patents — how much is proprietary, who pays for what and how much can be made public — must be settled case by case. Moreover, since administrators have traditionally felt a responsibility to protect public resources against private commercialization, they not only lack experience in dealing with it but are being asked to do a philosophical about-face.

A positive example is the NSF program of Engineering Research Centers — university-based cooperative ventures with industry. Here, government researchers work closely with industry on such projects as computer-aided design of dies and the manufacture of formed parts to near-final shape in as few steps as possible. This program must be expanded and proposals for other kinds of multidisciplinary centers must be enacted to help restore innovation in American industry.

particularly in manufacturing, which accounts for nearly all technological development in the U.S. As the Japanese have demonstrated, manufacturing remains the indispensable medium through which innovation comes to economic and social fruition.

There are other lessons to be learned from the industrialized nations of Europe and the Far East. In the years following World War II, they adopted a cooperative approach between government and industry in support of commercial development as a matter of economic survival.

Perhaps the best U.S. models are the states, which have a strong stake in the viability of local industry. The National Governors Association estimated that in 1987 states invested more than $700 million in a variety of innovative programs to expedite the commercialization of advanced technologies.

The mechanisms for greater cooperation are thus in place, and models are being developed. Coordination and leadership at the highest level, together with effective day-to-day implementation of existing mandates, must combine to ensure that the latest scientific advances are rapidly translated into products that fuel U.S. economic growth.

SUMMARY OF RECOMMENDATIONS

1 Strengthen funding for basic research through NIH.

2 Ensure the stability and continuity of funding that basic research, by its very nature, requires.

3 Provide adequate funding for the restoration of the nation's basic research infrastructure — university and research institute facilities, equipment and instrumentation.

4 Implement existing incentive programs for cooperative research between the three partners — government, academia and industry — and develop additional programs as needed.

5 Place a high priority on developing and disseminating the technology of advanced manufacturing. Encourage Federal laboratories to conduct research like that performed by the National Bureau of Standards in its Automated Manufacturing Research Facility. Expand NSF programs in engineering and manufacturing technology.

6 Adopt policies that facilitate cooperative projects and exchanges of scientists and information between government, academia and industry.

"Throughout history the patrons of science have understood the potential of new scientific knowledge as an instrument of public welfare, of power, of national security, and of national economic strength. Science has been faithful to that compact — that the American people for their support of science could in time expect a better life and a stronger nation."

Frank Press
President, National Academy of Sciences

Beginning as a one-room laboratory in the Marine Health Service Hospital on Staten Island, with an annual budget of $300, the NIH today occupies a 306-acre complex in Bethesda, Md., spends more than $5 billion a year on research — the bulk of it in academic grants — counts some 3,000 physicians and Ph.D. scientists among its close to 15,000 staff members and publishes more than 2,000 reports and scientific papers each year. The NIH operates the world's largest research hospital, where it conducts clinical studies on new therapies and treatments, generally with compounds supplied by industry.

NIH is an indispensable contributor to the medicines and therapies responsible for American preeminence in global markets:

- Thirty-eight NIH-funded scientists have won the Nobel prize in physiology and medicine — far more than from any other single institution.
- One-third of America's biomedical researchers have trained as postdoctoral fellows at NIH, including scores of Merck scientists.
- The achievements of NIH scientists have laid the foundations for a number of the industry's most revolutionary products.
- An NIH scientist was co-discoverer of the AIDS virus. NIH leadership in this area, as well as in cardiovascular and cancer research, is unparalleled.
- NIH provides about half the funding for the nation's basic biomedical research, primarily through grants to academic investigators — 25,000 in 1987.

THE PARTNERSHIP: A HEALTHY INTERCHANGE

The beneficial interchange of biomedical researchers and managers between academia, government and industry has been central to the Merck experience. At various stages in their careers, many of our scientists have taught in universities or conducted research for the government or independent research institutes.

The career pattern of Merck's chairman and CEO, P. Roy Vagelos, M.D., is typical. He interned at the Company for a summer as a medical student. After graduation, Dr. Vagelos conducted cardiovascular research at NIH, then went to Washington University of St. Louis, where he headed the biological chemistry department. An expert in lipid chemistry, he was an academic consultant to Merck before joining the Company in 1975 as senior vice president for research and development.

Edward Scolnick, Ph.D., President of Merck Sharp & Dohme Research Laboratories, also spent many years at NIH as a National Cancer Institute scientist, specializing in oncogene research.

Over the years, hundreds of scientists now at Merck have done postdoctoral research at NIH, conducted university research with NIH support or collaborated as Merck researchers with NIH and university scientists.

THE GROWING JAPANESE STAKE IN BASIC RESEARCH

Is support for basic research — the kind that builds the foundations of knowledge essential for new products — an important national priority? Ask the Japanese. Over the past decade, Japan has tripled its basic research budget.

Although a latecomer to this area, the Japanese have made basic research a national priority. Some 13% of the country's total R&D spending now goes for basic research, as compared with 12.2% in the U.S. Scientific journal citations of Japanese research have increased 25% in the past decade.

Japanese pharmaceutical companies, which until recently had little or no tradition of basic research, have begun to invest substantially in this activity. Japan's third largest pharmaceutical firm has opened research centers in the U.S. and West Germany, and Japan's share of the world's new pharmaceutical patents jumped from 1% to 20% in the decade from 1973 to 1983. Japanese companies are recruiting Japanese and American researchers from U.S. laboratories, working directly with American universities on basic research and negotiating licensing agreements with American biotechnology firms.

Since the turn of the century, the medical profession has suspected excess cholesterol in the blood as a primary cause of coronary artery disease, the killer of more Americans — some half million annually — than any other disorder. Nevertheless, to validate their suspicion, researchers had to prove three theories:

- People with low levels of cholesterol in their blood rarely suffer heart attacks.
- It is possible to reduce blood cholesterol levels safely with a medicine.
- Use of such a medicine will reduce the heart attack risk.

To validate the first hypothesis (and others relating to cardiovascular disease), NIH scientists began, in 1948, to study the entire population of Framingham, Massachusetts — work that continues to this day. Starting in the mid-1950's, the study began generating a series of reports showing a strong correlation between low cholesterol and a low risk of coronary artery disease.

In 1956, Merck scientists introduced the first drug to safely lower the level of serum cholesterol. Assigned the chemical name "cholestyramine," it was unpleasant and inconvenient to take — like swallowing a heaping tablespoon of sand suspended in water three times a day. And its initial side effects, while not dangerous, could be uncomfortable. So we licensed it to another firm while continuing to work toward a better drug. Nevertheless, cholestyramine did safely reduce serum cholesterol by an average of 10-15%.

Using cholestyramine, NIH investigators launched a seven-year study of 3,500 volunteers with high levels of serum cholesterol. The results provided the balance of proof needed to demonstrate beyond all doubt the lethal role of excess cholesterol and the lifesaving implications of bringing it under control. Specifically, NIH researchers were able to show that a 1% reduction in serum cholesterol lowers the risk of heart attack by 2%.

By coincidence, publication of that proof in 1984 came just as Merck's scientists were developing a far more effective and convenient cholesterol-lowering drug, 'Mevacor.'

There can be little doubt that the many years and millions of dollars invested by NIH in epidemiological and clinical research on cholesterol have added significantly to medical and public appreciation of the value of 'Mevacor' and its likely impact on public health.

One way Merck contributes to basic research is by funding grants to universities and independent biomedical research institutes. Money allocated for this purpose increased from half a million dollars in 1986 to nearly $2.4 million in 1987, the majority of the grants going for individual postdoctoral fellowships. In addition, more than 300 university lecturers were invited to speak at Merck in 1987.

The partnership works for everyone. To cite just one example from Merck's experience, 'Recombivax,' the first recombinant vaccine, was made possible through collaboration with genetic engineers at the University of California, San Francisco, and the University of Washington. And — a perfect demonstration of the tripartite relationship — these scientists earned their reputations through achievements in basic research funded by NIH.

The decline of science and mathematics education in America's schools and colleges is a serious threat to the nation's ability to compete. The scientists and engineers needed for industry and research are not being trained. Nor are tomorrow's leaders being equipped with the scientific literacy needed to make crucial policy judgments about the environment, energy, space and biotechnology.

The skill, dexterity and knowledge of a nation's people is the most powerful engine of its economic growth.

Adam Smith

Those who remember Sputnik — the first space satellite, sent aloft by the Soviets in 1957 — also remember being jolted out of their complacency. The U.S. was technologically unprepared for the space age. A watershed event, the Soviet scientific coup set in motion a major reappraisal of American education and imparted a new priority to training for careers in science and engineering.

Now, 30 years later, America finds itself once again at the crossroads. Can the nation's educational system respond to the challenge to maintain American technological leadership in an increasingly competitive world? Who will reap the economic and cultural benefits of tomorrow's breakthrough products?

"In the past, U.S. leadership in the world arena has been a function of U.S. leadership in technology — this will be even more true in the future."

Representative Manuel Lujan, Jr. (R-NM)

The decline of science education in the United States, from kindergarten through college, threatens the quality and quantity of the industrial innovation on which the American standard of living and way of life depend.

Moreover, foreign nationals are earning a greater proportion of graduate science degrees than ever before, not only because they are streaming to U.S. colleges and universities in greatly increasing numbers, but also because American students are not opting for science and engineering careers.

American universities and industry welcome the skills and expertise of scientific minds from throughout the world, and foreign students have proved to be a strong

asset to U.S. research efforts. A report sponsored by the National Academy of Engineering concluded that "without the use of noncitizen and foreign-born engineers, both research universities and industries would have difficulties in handling the educational, research, development and technological programs that are currently supported."

Nonetheless, it is essential to develop native talent on which the nation can depend. The engineering report attributes the decline to "faulty policies and serious deficiencies in the U.S. educational and value systems" and urges "a significant improvement in [the] entire educational system."

"Our nation faces two important challenges for the future. We must compete with the Soviet Union to maintain a strong defense and to keep a secure peace, and at the same time we must compete with many other nations to ensure a healthy economic future. Meeting both challenges will depend on Americans continuing to be the world's best researchers, the world's brightest inventors and the world's most skilled workers."

Senator Patrick Leahy (D-VT)

High-technology industry also demands workers who are literate and have the mathematical skills to function in a high-tech environment. All available evidence indicates that U.S. schools are far less capable of providing that level of education than those in most other industrialized societies. A recent Federal study concluded that up to 23 million Americans in the work force lack the basic reading, writing and mathematical skills to compete in today's job market. It is imperative that American government at all levels address this problem now. The importance of a literate, educated work force cannot be overstated.

In addition, business should be encouraged to systematically integrate training and retraining into its normal planning and operations, while improving the linkage between employees and schools and universities.

These improvements are critical not only for training a technologically literate work force, but also for educating the executives and managers who will guide the nation's industries.

Equally disturbing is the lack of general scientific and mathematical literacy that would ensure wider public understanding of and support for technological progress. As F. H. Westheimer, Morris Loeb Professor of Chemistry, Emeritus, at Harvard University, observed, today's graduates are tomorrow's decision makers:

> They will have to exert judgments on problems concerning the safety of nuclear energy plants, the desirable and undesirable effects of specific chemicals in our society, the dangers and advantages of genetic engineering . . . and dozens of other questions . . . . It will serve our students and the nation well if they know enough science to provide them with a background for future learning, and if they can at least listen intelligently to the arguments of experts; perhaps they will even be able to distinguish them from purported experts. Lack of knowledge will not prevent them from having opinions; it will only prevent them from having informed opinions.

Let us hope that the data presented on these pages, and by such groups as the White House Science Council, the National Science Foundation (NSF) and the Council on Research and Technology (CORETECH), prove sufficiently compelling to motivate support for a substantially augmented investment in science and technology education. *(See sidebar: "The Decline of Science Education in the U.S.")*

Corporations have tried to help at both university and precollege levels. Industry funded approximately 8% of all university research in 1987, and that figure is expected to increase to 10-12% by the 1990's. A number of corporations have helped create special science and technology high schools. Others have donated money and equipment, part-time instructors, internships and summer job opportunities as part of "adopt-a-school" programs. *(See sidebar: ". . . Schools and Colleges.")*

But the crisis cannot be solved by corporate support or university fund-raising alone. The White House Science Council Report on the Health of U.S. Colleges and Universities, recommending that the Federal government make "substantially greater investments in our centers of learning in the 1980's and 1990's," stated: "Our universities today simply cannot respond to society's expectation for them to discharge their responsibilities in research and education without substantially increased support."

Government leadership in this area has been slow to develop. In other countries, public policy affecting science education is centralized and capable of focusing intellectual and financial resources on specific goals. Canada, for example, encourages grants to postgraduate students by allowing them to double and even quadruple their grant dollar with funds from other sources, including the central government.

The White House Science Council Report also urged the establishment of multidisciplinary centers:

> The strength of the nation in trade, defense and health has been directly related to past investments in science and technology. Our future position in global markets will similarly depend on our willingness to respond to opportunity and to mobilize our strengths today. To this end, we must promote a broad interdisciplinary approach to problem-solving by focusing on university-based centers that will improve cooperative linkages between scientists, engineers and industry.

These university-based complexes would bring together government, industrial and university expertise to solve problems related to broad national needs and would supplement other university-based programs operating from existing departments and divisions.

The report calls for a renewal of the partnership as essential to our national interest:

> We are certainly not alone in recognizing that science and technology are critical to our future. Nations everywhere are investing in these capabilities. We conclude that we must rethink and, in many ways, rebuild the critically important interactions between universities, government and industry that have served this Nation so well in the past. The Federal government-university relationship is too fundamental to the maintenance of our national science and technology base to be taken for granted, and the industry-university partnership is emerging as critical to exploiting that base in order to compete in the world marketplace.

SUMMARY OF RECOMMENDATIONS

1 Significantly increase Federal support for basic research in universities and colleges.

2 Increase Federal support for scholarships, fellowships and other programs to attract more of our brightest students to science careers, including research and teaching.

3 Encourage our nation's schools, colleges and universities to strengthen science and mathematics components of their core curricula.

4 Raise minimum standards of education to ensure that all students master the basic literacy and mathematical skills needed to function in a technologically evolving, highly competitive world.

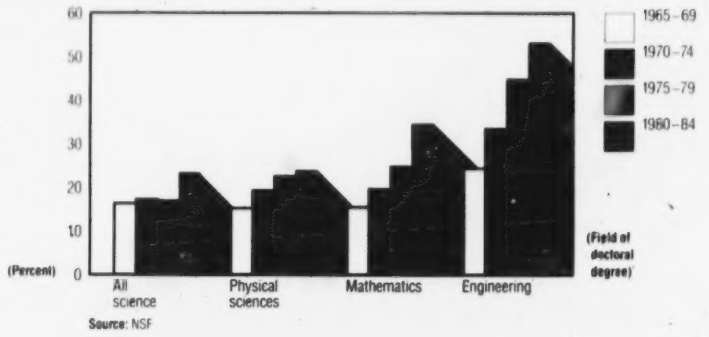
5 Modernize public education and training. Encourage business to make training and retraining systematically integral to its operations. Make education and training more relevant by anticipating market demands and encouraging mutually supportive linkages between business and educational institutions at all levels.

6 Enhance cooperative research by providing funding and incentives for university-based science and technology centers similar to those now being established in New Jersey and other states, centers that work with state government and industry in research areas of national importance.

7 Strengthen similar programs in existing university departments and divisions.

8 Restore and refurbish academic research facilities, equipment and instrumentation.

DOCTORAL DEGREES AWARDED TO FOREIGN CITIZENS BY U.S. UNIVERSITIES, 1965–1985



THE DECLINE OF SCIENCE EDUCATION IN THE U.S.

The warning signs are everywhere — in declining enrollment figures for the sciences, in critical assessments of curricula and teachers, in low test scores and in deteriorating laboratories and facilities:

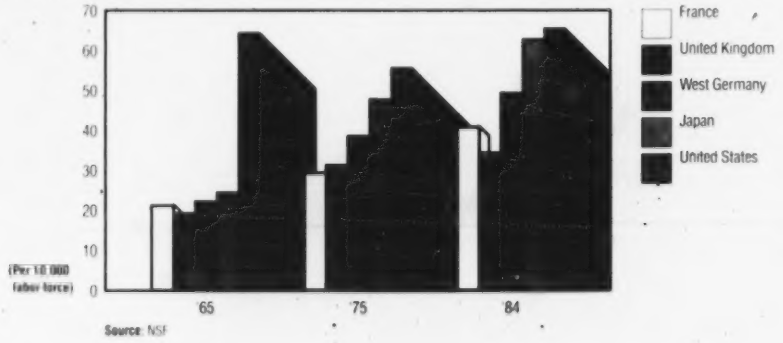
- In the 1960s, the United States led its competitors in the number of scientists and engineers per capita. Japan, with half the population, now produces more engineers than the U.S. Only about 7 out of every thousand American students receive an engineering degree, while in Japan, the figure is 40.
- Over the last decade, the proportion of U.S. undergraduates majoring in the sciences and engineering and U.S. citizens receiving advanced degrees in these areas has declined. More than half the new Ph.D.s in engineering in the U.S. are awarded to foreign nationals. The same is true of mathematics and physics doctorates.

There are about 1,600 vacant engineering faculty positions at universities, and half have gone unfilled since 1984.

In the life sciences, the number of Ph.D.s conferred remains about the same as a decade ago. Master's degrees, however, have declined by nearly one-quarter and undergraduate degrees by nearly 30%.

- The number of foreign students earning U.S. graduate degrees in the life sciences nearly doubled between 1975 and 1985, going from approximately 6,500 to about 12,000.

R&D SCIENTISTS AND ENGINEERS PER 10,000 LABOR FORCE POPULATION FOR SELECTED COUNTRIES, 1965, 1975, 1984



PRE-COLLEGE SCIENCE ACHIEVEMENT IN 17 COUNTRIES

Rank Order	Grade 4/5	Grade 8/9	Grade 12/13		
1	Japan, Korea	Hungary	Singapore	Hong Kong	Hong Kong
2	—	Japan	England	England	England
3	Finland	Netherlands	Hungary	Singapore	Hungary
4	Sweden	Canada	Poland	Japan	Japan
5	Hungary	Finland	Hong Kong	Hungary	Singapore
6	Canada	Sweden	Norway	Australia	Norway
7	Italy	Korea, Poland	Finland	Poland	Poland
8	U.S.A.	—	Sweden	Norway	Australia
9	Australia	Norway	Australia	Sweden	U.S.A.
10	Norway	Australia	Japan	Italy	Sweden
11	Poland	England, Italy	Canada	U.S.A.	Canada
12	England	—	Italy	Canada	Finland
13	Hong Kong, Singapore	—	U.S.A.	Finland	Italy
14	—	Singapore, Thailand, U.S.A.	—	—	—
15	Philippines	—	—	—	—
16	—	Hong Kong	—	—	—
17	—	Philippines	—	—	—
Total	15	17	13	13	13

Colleges have not fared much better. The National Science Board's 1986 report on undergraduate science and engineering education issued this dire warning:

> The deterioration of collegiate science, mathematics and engineering education is a grave long-term threat to the nation's scientific and technical capacity, its industrial and economic competitiveness and the strength of its national defense.

The report urged that highest priorities be accorded to:

1 The quality of laboratory instruction and the condition of instrumentation and facilities

2 Faculty teaching skills and command of new technology

3 The upgrading of courses and curricula, which were criticized as out-of-date and unimaginative.

Dozens of reports have brought to light the glaring deficiencies in U.S. public schools:

- A National Science Teachers Association survey found that a third of the country's high schools offered no physics courses, a fifth offered no chemistry, a tenth no biology and almost three-fourths no earth or space science.
- The Carnegie Corporation's Forum on Education and the Economy reported in 1986 that the system of precollege education in the sciences was so badly in need of repair that it should be rebuilt from the ground up. Science and mathematics teachers are poorly trained, classroom equipment is inadequate and out-of-date, and women and minority students receive little encouragement to pursue the sciences.
- Preliminary reports of the Second International Science Study published in 1988 called for the complete reexamination of science education methods in the United States. The nation's students scored extremely low compared to their peers from 23 other technologically advanced countries. On these tests, conducted between 1983 and 1986 by the International Association for the Evaluation of Educational Achievement:

U.S. fifth-graders ranked 8th overall among those from 15 countries.

Ninth-graders ranked 14th out of those in 17 nations.

Results did not improve at the secondary level. In a field of 13 countries:

U.S. high school seniors in advanced physics ranked 9th.

Advanced chemistry students placed 11th.

Advanced biology students finished last.

- American students from kindergarten to college score significantly lower than those of other industrialized nations in international examinations in mathematics — the foundation discipline for science and an indicator of future competitiveness:

Non-U.S. citizens who take the Graduate Record Examination in mathematics average 100 points higher than U.S. students.

The top 5% of U.S. high school seniors scored lower on mathematics tests than those of eight other industrialized nations; the average 12th grade Japanese student did better than 95% of comparable U.S. students.

U.S. eighth-graders are well below international norms in problem-solving skills.

Differences in mathematical achievement between U.S. and foreign students are apparent as early as the primary grades.

- A literacy assessment of young adults, as described in a 1988 study issued by the U.S. Secretaries of Commerce, Education and Labor, *The Bottom Line: Basic Skills in the Workplace*, revealed that:

Only 27% could interpret a lengthy feature story in a newspaper.

28% were unable to write a letter to state that an error had been made in billing.

Only 25% of black young adults and 41% of Hispanics — compared to 61% of whites — could be classified as "adept" readers; that is, able to find, understand, summarize and explain relatively complicated information.

These trends are exacerbated by other factors. The number of 22-year-olds in the population has been declining since 1983. The NSF estimates that there will be 25% fewer college-age Americans by the turn of the century. At the same time, science and engineering employment has greatly increased since 1980.

Where will the next generation of American scientists come from? Unless a greater proportion of students pursue science and engineering degrees, the numbers will decline dramatically. The NSF estimates that just to maintain present numbers, U.S. schools and universities may need to attract 50% more students.

And who will teach these students if they are found? According to Bill G. Aldridge, executive director of the

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"The data paint a dismal picture of science education in the United States today. But American children have just as much native curiosity and capacity for learning about science as children in any nation. We must develop quickly the national will to improve the effectiveness of science education in American schools. All segments of our society must work together to nurture our children's curiosity and to provide for them teachers, materials and surroundings that help them to learn science."

Bassam Z. Shakhashiri
Assistant Director, Science and Engineering Education
National Science Foundation

National Science Teachers Association, some 30-40% of all science courses in American high schools are staffed by "drastically unqualified" teachers. At the university level, science and engineering faculty are in demand by industry, and serious shortages are already occurring. The U.S. Department of Education projects a declining supply of teachers at all levels. In 1988, approximately 85% of the demand will be met; in 1992, only 66% — two-thirds of the number thought to be needed. And that says nothing about quality.

Are there any positive signs? One small but potentially encouraging indicator is the number of students taking College Board Advanced Placement examinations in the sciences. Although the scores have not increased since 1984 (in fact, they are slightly down), the numbers have. In May 1984, 19,387 students took the biology examination. In 1987, that figure was 28,415, an increase of nearly 50%. The number of chemistry and mathematics test takers also went up by 40-50%.

But this is a drop in the competitive bucket. The nation must summon the resources to attract the best students and teachers to U.S. schools and universities, prepare teachers adequately, refurbish their surroundings and update the equipment with which they learn, teach and conduct research.

STRENGTHENING THE PARTNERSHIP: AMBASSADORS TO ACADEMIA

For millennia the university was the home of science, industry was the home of technology, and potentially useful scientific discoveries had to wait decades, even centuries, to find practical application. During the 20th century, however, the gap between science and technology narrowed, and it continues to shrink in two ways.

First, the time between the creation of new knowledge and its incorporation into new products and processes grows ever shorter. It took more than a half century for Faraday's discoveries to produce a practical electrical generator, two decades to turn Watson's and Crick's discovery of the double-helix structure of DNA into genetic engineering, but only six years to make transistors out of Esaki's discovery that electrons can tunnel through solid matter. This trend can be expected to continue.

Second, the division of labor between academic and industrial scientists is no longer as clear-cut as it once was. Academicians still spend most of their time learning how nature works, and industrial scientists still spend most of theirs trying to put new knowledge of nature to practical use. But it is no longer unusual to find professors applying for patents or industrial researchers publishing in scientific journals. What's more, the computer and other new research tools are beginning to make scientific discovery itself a kind of technology.

The effect has been to bring science and technology, learning and manufacturing, the university and the company closer together. Merck's Ambassador Program is one example of the growing number of industry-university liaisons that offer something for both industry and education.

Launched in the late 1970's, the Ambassador Program enables top scientists from the Merck Sharp & Dohme Research Laboratories to maintain close contact with research universities. Visiting some 35 major schools across the country, these scientists (usually alumni of the schools they visit) discuss areas of mutual research interest with faculty members and graduate students and describe career opportunities at Merck.

Other programs encouraging extensive interactions with academia range from grants for basic research to post-doctoral fellowships, consultantships and research collaborations.

Through these interactions, we hope to inspire — and ultimately hire — gifted men and women. Specifically, it is our corporate aim both to expand the quality and size of the talent pool from which we draw new employees and to increase the proportion of those hired directly from school.

The program's success has prompted plans for its expansion to include ambassadors from throughout the company, not just the research division.

STRENGTHENING THE PARTNERSHIP: SCHOOLS AND COLLEGES

In its charitable giving, Merck places first priority on the need for the revival and enhancement of science education. Since 1957, when The Merck Company Foundation was established, the Foundation has made cash contributions of more than $57 million — most of it in grants to higher education in medicine and health-related sciences — through programs initiated by the Foundation. In 1987, the Company and the Foundation made educational grants totalling $7.2 million.

Merck has also contributed to state and local efforts to improve education. In New Jersey, our headquarters state, the Governor and Commissioner of Education have drawn upon Merck and other corporate resources in developing a number of innovative policies in science education. The Company also supports programs for science teachers in urban districts and was instrumental in organizing a special commission to examine how corporations and others can assist the educational process. Science teachers work with Merck scientists during the summer to revise curricula, and scientists visit the teachers' classrooms during the year.

The Company has also sought to help by supporting such efforts as the New Jersey Center for Advanced Biotechnology and Medicine, a center for basic research in molecular biology as well as for clinical research, funded by the state and Federal government together with industry.

VI. RESTRUCTURING TAX POLICY

It is an economic principle universally recognized that without tax and other economic incentives, industrial research and development would be chronically underfunded. America's economic rivals have structured their tax policies to provide stable, consistent long-term incentives for industrial R&D. The U.S. should do the same.

Why should government provide incentives for industrial research and development? Doesn't management realize how essential R&D is to the growth of a high-tech industry? Left to their own devices, without any special tax incentives, wouldn't companies invest as much in R&D as they do now?

Herbert Simon, Nobelist in economics, provides an answer:
It is an elementary principle of economics that a society's basic research and development cannot be left entirely to private industry, because then there would always be under-investment in R&D. Many of the economic benefits of R&D cannot be captured by the developer, and he will not take account of . . . [the] valuable public goods that flow from his efforts in his investment decisions. It is good economics, as well as good public policy, to provide substantial public subsidy for research and development.

Although economists rarely agree, on this point they are virtually unanimous: the market, acting alone, creates chronic under-investment in R&D. The situation is further aggravated, they say, by the high risk associated with R&D projects. Fully 80% are believed to be economic failures. In the pharmaceutical industry, for example, two out of three products never recover the cost of their development ($125 million on average). These products may be important medically, but they are not profitable.

TAX INCENTIVES FOR R&D IN U.S. POLICY

Currently the U.S. government has two tax provisions that encourage industrial R&D:

- A *tax credit* on current-year earnings spent on R&D
- A *deduction* from taxable income of current-year earnings spent on R&D.

(Firms that in the main operate domestically may take the full deduction. Most firms with substantial overseas operations are currently limited to a deduction of less than the full R&D expenditure.)

The Incremental Tax Credit

The R&D tax credit may be claimed only for *increases* in R&D spending above a company's average R&D spending for the prior three-year period. Thus, economists noted, the actual value of the 25% credit was only 7%. Initially adopted in 1981 as part of the Economic Recovery Tax Act, the credit was in effect during a period of dramatic gains in private R&D investment, from $30.9 billion in 1980 to nearly $60 billion in 1986. In the health care industry, the investment of PMA-member companies in R&D more than doubled from $2.2 billion to $4.6 billion.

"Over the next five years, our manufacturing output will have to grow more than 30 percent, . . . 15 percent to close the trade deficit, . . . another 15 percent to meet the needs of a growing domestic economy. [This] implies a much more rapid growth . . . than we have sustained for a long time. And that growth has to be concentrated in new products and advanced products, where we can have an edge in world markets."

Paul Volcker
Former Chairman, Federal Reserve Board

The original R&D credit provision expired at the end of 1985. It was reenacted in 1986 but reduced from 25% to 20%; accordingly, its true effective value fell to between 4% and 4.5%. R&D spending continued to increase, but at a reduced rate: 9% overall in 1986 as compared with a 12% rise in 1985. The 20% incremental credit was due, in turn, to expire at the end of 1988. We recommend that some measure of this incentive be restored and made a permanent part of tax law.

The 25% incremental credit enacted in 1981 clearly demonstrated its value to the economy. According to a 1987 Brookings Institution study commissioned by the Council on Research and Technology:

- The ratio of R&D to output grew more than twice as rapidly as it did in the five years prior to enactment of the credit.
- By 1985, American manufacturing was 20% more R&D-intensive than it had been in 1980.
- By 1986, aggregate U.S. R&D spending was about 7% higher than would have been expected. Since R&D has a very high social return, the increase is estimated to have added between $8 and $13 billion to the GNP over the five years the credit was in effect.
- Had it been retained, the 25% credit would have more than paid for itself, boosting GNP by perhaps as much as $17 billion annually by 1991.

In addition to the authors of the Brookings Institution study, other supporters of a stable credit include the authors of studies conducted for the Congressional Research Service, the Joint Economic Committee and the President's Commission on International Competitiveness.

Alterations in the design of the R&D tax credit have been proposed from time to time. Some, like the tightening of the definition of eligible R&D, were adopted

when the credit was extended at 20% in 1986. Other modifications were proposed at the time, but not enacted. Chief among these was a proposal to extend the credit to start-up ventures, a move we strongly endorse. We also support extending credit to the development of manufacturing *processes* for new or improved products.

The Basic Research Credit

The 1986 Tax Reform Act contained another promising R&D incentive: a Basic Research Credit to encourage industry support of such research at universities and other institutions. Unfortunately, this credit was set to expire at the end of 1988. Two years, of course, will not suffice to demonstrate the credit's impact on a category of research that requires a long-term commitment.

In addition to basic research at universities, we believe that all types of cooperative basic research should be eligible for the credit, including that conducted by industrial consortia. Such groups play an important role in speeding the transfer of technology from the laboratory to the marketplace.

"Does spending to maintain creative research programs and training . . . contribute to our being competitive? In our technology-based world, . . . there is no question that we would quickly drop out of sight without the creative impulses provided in our universities as vigorous R&D and training enterprises. . . . But that is not enough. Someone must also look at the structure of our domestic and international business to promote legislation that will promote our competitiveness."

Lawrence Bogorad
Maria Moors Cabot Professor of Biology, Harvard University
Chairman, Board of Directors, American Association for the Advancement of Science

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TAX DISINCENTIVES FOR R&D IN U.S. POLICY

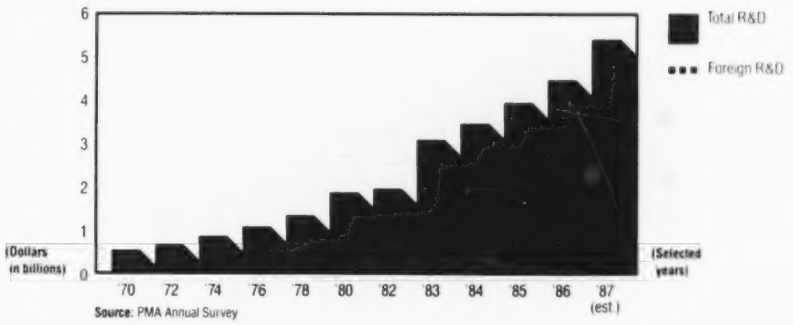
Are there tax disincentives to research in the United States? The answer is yes, and in the industrialized world they are virtually unique to this country.

Taxation of Multinationals

Section 1.861-8 of the Treasury Department's income tax regulations, which deal with allocating expenses for purposes of determining the amount of foreign taxes a U.S. company can credit on its U.S. tax return, functions as a disincentive to domestic research and development. The regulation, in effect, allows U.S. companies with substantial foreign operations to deduct from their U.S. taxes only a portion of the earnings they invest in R&D.

The complex interaction between current U.S. Treasury regulations and the tax policies of other nations penalizes R&D done in the U.S. and encourages U.S.-based multinationals to expand foreign R&D operations at the expense of R&D operations in the U.S.

FOREIGN VS. DOMESTIC R&D INVESTMENT BY U.S. PHARMACEUTICAL INDUSTRY, 1970–1987



Recognizing the potential for harm in the regulation, Congress placed temporary moratoria on its implementation. However, the last of these expired in August 1987.

If all U.S. firms were permitted to deduct 100% of expenditures for R&D activity in the U.S., and all other factors remained unchanged, Federal revenues would decline by an estimated $5.42 billion over five years. A drop of this magnitude in a time of record Federal budget deficits clearly would not be in the public interest. Consequently, we favor a compromise. For example, the Treasury Department, the House and the Senate have submitted proposals that would allow companies to deduct approximately two-thirds of their U.S. R&D expenses. The remaining third would be allocated between foreign income (thus rendered non-deductible, in effect) and domestic income (thus still deductible). With these changes, the mechanics of the foreign tax credit computation would undercut the deductibility of R&D expenditures to a much lesser extent than under current law.

Such a compromise would reduce Federal revenues by an estimated $3.26 billion over five years, but this sum would be offset in the long run by the economic benefits of a more extensive research effort. Short-term, it could be reduced by tax increases in less critical areas or through Congress's budget reconciliation process.

This compromise would discourage further movement of U.S. R&D resources abroad, where no such disincentives exist and where powerful incentives are in place to attract and encourage R&D. *(See sidebar: "What Other Nations Are Doing.")*

SUMMARY OF RECOMMENDATIONS

1 Make the R&D tax credit a permanent provision of the code. Extend the credit to start-up ventures and to the development of processes for the manufacture of new or improved products.

2 Make the Basic Research Credit a permanent part of the code and extend the credit to industry consortia.

3 Resolve the issues raised by Section 1.861-8 of the Treasury Department's income tax regulations with a compromise that permanently sets the percentage of R&D expenses for allocation against U.S. income at approximately two-thirds.

How does the U.S. tax structure with its inconsistencies and short-term variations compare with those of America's competitors — Japan, South Korea, Taiwan, Canada, the United Kingdom, Ireland, West Germany and France — when it comes to encouraging R&D?

Deduction of Current-Year Earnings Spent on R&D
Except for South Korea and Taiwan, all of these nations allow a full deduction for R&D, and many make capital as well as current expenditures eligible. Japan and the United Kingdom permit unused deductions to be carried over for up to five years. Canada sets no time limit on carryover and allows immediate expensing for both current and capital expenditures on R&D.

At a company's option, R&D expenditures in South Korea may be treated either as deferred assets to be amortized over a five-year period or as a one-time expense. In the case of amortization, residual value is zero.

Special Tax Deductions
The Japanese tax code allows a tax deduction equal to 25% of income from the sale of technology abroad in the form of patents or know-how.

Reduced Tax Rates
In Taiwan, research-intensive industries are eligible for a reduced corporate income tax rate of 22%.

Tax Credits
The tax code of France provides for a 25% incremental tax credit very comparable in design to that of the U.S. The major difference is that, in France, the rate remains stable at 25%.

Uniquely among these nations, Canada provides for a flat 20% tax credit on current-year spending on R&D activities. Japan offers a tax credit of up to 10% of current year taxes for R&D expenditures, which may include depreciation and overhead. The credit is equal to 20% of the excess of current R&D spending over and above the largest single-year investment in R&D since 1966, provided the amount does not exceed the 10% limitation.

In Taiwan, equipment or machinery purchased by a research-intensive firm qualifies for an investment tax credit of 15% if domestically produced, 5% if imported.

Depreciation Allowances
South Korea offers certain research-intensive industries a special depreciation allowance: 100% over the useful life of the equipment or an investment credit of 3-6%, depending on whether

the invested asset is imported or domestically produced. Firms that acquire facilities for R&D or for professional training may receive a special benefit of up to 90% depreciation of the acquisition costs or an 8-10% tax credit, at the taxpayer's option.

South Korean firms also receive a tax advantage for the industrialization of research results originated by certain domestic research institutes: either a one-time additional depreciation of half the invested assets or an investment tax credit of 6%; 10% if the project uses equipment of domestic manufacture.

In Taiwan, R&D equipment qualifies for accelerated depreciation, and equipment with a useful life of ten years or less may be depreciated within one-half that time. As an alternative to accelerated depreciation, approved firms may opt for a four-year tax holiday on incentive income.

In West Germany, depreciation of R&D assets may be accelerated at rates of up to 40% on personal property.

The tax code of France provides for accelerated depreciation in the first year of service of R&D assets.

Cash Grants

West Germany provides for a cash payment of up to 20% on the first $170,000 and 7.5% on the balance spent in any given year on depreciable assets (including real property) used for R&D purposes. This tax credit does not reduce the amount of the R&D deductions otherwise available. French companies that create or expand their R&D departments receive cash grants equal to 15-20% of the expenditure, up to a maximum of $4,464 per job created.

Other Special Tax Breaks for R&D

In South Korea, certain high-tech industries qualify for a tax break equal to 1.5% of revenue or 30% of taxable income if they have programs to develop the technologies on which they are based. The Irish tax code provides for current-year capital allowances of 100% for machinery and equipment, and 10-15% for buildings used for R&D. Royalty income from patented products generated by domestic R&D is tax-free.

LIST OF CHARTS AND GRAPHS

Introduction: Innovation and Incentive

"Foreign Goods in U.S. Market." Source: Commerce Department.

"U.S. Trade Balance in High-Technology and Other Manufactured Product Groups." Source: Science and Engineering Indicators — 1987.

"Patents: An Index of Innovation." Source: NSF.

"Non-Defense R&D Expenditures as a Percent of Gross National Product (GNP) by Country." Source: Science and Engineering Indicators — 1987.

"Science and Technology Policies and Priorities: A Comparative Analysis." Source: Special Analytical Studies Section, Division of Science Resource Studies, NSF.

"National Support for Health R&D by Source, 1977-1987." Source: NIH.

II. Empowering FDA

"Drug Development Times in U.S. and Abroad." Source: PMA Annual Survey.

"FDA Administration Budgets, 1979-1986." Source: FDA.

"FDA Personnel Totals, Selected Years, 1976-87." Source: FDA.

"FDA Review Times for New Molecular Entities." Source: FDA.

"New Molecular Entity Backlog." Source: FDA.

"The Steps Toward Drug Approval." Source: PMA.

III. Enacting Tort Reform

"Million-Dollar Jury Verdicts for Product Liability." Source: Jury Verdict Research, Inc.

IV. Supporting Research

"U.S. Patents Granted, by Nationality of Inventor and Date of Application." Source: Science and Engineering Indicators — 1987.

"Basic Research as a Percent of Total Federal R&D." Source: NSF.

"Military R&D as a Proportion of All Federal R&D." Source: OMB.

"Federal Obligations for R&D Plant to Universities and Colleges: Fiscal Years 1965-1988 (est.)." Source: NSF.

V. Revitalizing Science Education

"Doctoral Degrees Awarded to Foreign Citizens by U.S. Universities, 1965-1985." Source: NSF.

"R&D Scientists and Engineers Per 10,000 Labor Force Population For Selected Countries: 1965, 1975, 1984." Source: NSF.

"Pre-College Science Achievement in 17 Countries." Source: International Association for the Evaluation of Educational Achievement and NSF.

VI. Restructuring Tax Policy

"Foreign vs. Domestic R&D Investment By U.S. Pharmaceutical Industry, 1970-1987." Source: PMA Annual Survey

BIBLIOGRAPHY

INTRODUCTION: INNOVATION AND INCENTIVE

Ambler, Dr. Ernest, et al. *The Status of Emerging Technologies: An Economic/Technological Assessment To The Year 2000.* Gaithersburg, Md.: National Bureau of Standards, June 1987.

American Association for the Advancement of Science. *R&D in FY 1988: R&D Policies, Budgets and Economic Competitiveness.* Colloquium Proceedings. Washington, D.C., 9-10 April 1987.

Barber, Elinor G., and Robert P. Morgan. "Impact of Foreign Graduate Students on Engineering Education in the United States." *Science*, 3 April 1987, pp. 33-37.

Computer Horizons, Inc. *Identifying Areas of Leading Edge Japanese Science and Technology.* (Final Report.) Cherry Hill, N.J., 15 April 1988.

_____. *Identifying Areas of Strength and Excellence in U.K. Technology.* Cherry Hill, N.J., 20 February 1987.

Council On Research and Technology (CORETECH). *National Research and Development Policies for 1988 and Beyond: The CORETECH Agenda.* Washington, D.C.: CORETECH, 1988.

"Government Money Buoys U.S. Spending on New Technology." *Christian Science Monitor*, 5 January 1988.

Jasinowski, Jerry J. *Competing in the Global Economy.* Washington, D.C.: National Association of Manufacturers, April 1987.

_____. "Why Manufacturing Is Essential to the American Economy." In *Washington Economic and Policy Trends.* Washington, D.C.: National Association of Manufacturers, August 1987, pp. 1-9.

Lederman, Leonard L. "Science and Technology Policies and Priorities: A Comparative Analysis." *Science*, 4 September 1987, pp. 1125-1133.

National Institutes of Health. *NIH Data Book.* Bethesda, Md.: U.S. Department of Health and Human Services. December 1987; updated 1988, personal communication.

_____. *Then and Now: Biomedical Science in 1887 and Today.* Bethesda, Md.: National Institute of General Medical Sciences, January 1987.

_____. *A Century of Science for Health.* 1987.

National Pharmaceutical Council. *The Effectiveness of Medicines in Containing Health Care Costs: Impact of Innovation, Regulation and Quality.* Washington, D.C.: National Pharmaceutical Council, 1982.

National Science Board. *Science and Engineering Indicators — 1987.* Washington, D.C., 1987.

National Science Foundation. *Annual Report 1986.* Washington, D.C., 1987.

_____. *Basic Research: The Key to Economic Competitiveness.* Washington, D.C., 1986.

_____. "Testimony of Mr. Erich Bloch, Director, National Science Foundation, to the Senate Armed Services Committee — Subcommittee on Defense Industry and Technology." 9 March 1987.

_____. "Testimony of Mr. Erich Bloch, Director, National Science Foundation, to the Joint Economic Committee, U.S. Congress." 2 December 1987.

"Nobel Prize for Theory of Economic Growth." *Science*, 6 November 1987, p. 238.

"Novel Technique Shows Japanese Outpace Americans in Innovation." *The New York Times*, 7 March 1988.

Office of Science and Technology Policy. *Report of the White House Science Council, Panel on the Health of U.S. Colleges and Universities*. Washington, D.C.: Executive Office of the President, February 1986.

Office of Technology Assessment. *Research Funding as an Investment: Can We Measure the Returns? — A Technical Memorandum*. Washington, D.C.: U.S. Congress, OTA-TMSET-36, April 1986.

Pharmaceutical Manufacturers Association. *1985-1986 PMA Annual Survey*. Washington, D.C., 1987.

____. *Facts At A Glance*. Washington, D.C., 1987.

____. *Fulfilling The Promise*. Washington, D.C., 1987.

____. "Drug Imports Up 21.5%; Exports 4.2%; Balance of Trade Halved in 1987." *PMA Newsletter*, 14 March 1988.

"Taking On The World." *Time*, 19 October 1987, pp. 46-47.

"The Twenty-Year Decline in Worldwide Drug Development." *Medical Marketing and Media*, August 1983.

The White House. "Facilitating Access to Science and Technology." Executive Orders, No. 12591, 10 April 1987.

Vagelos, P. Roy, M.D. "R&D: Good Medicine for the World." *Across The Board*, Vol. 24, No. 5, May 1987.

White, Craig C., M.D., et al. "Benefits, Risks and Costs of Immunization for Measles, Mumps and Rubella." *American Journal of Public Health*, July 1985, Vol. 75, No. 7, pp. 739-745.

Wiggins, Steven, N. *The Cost of Developing a New Drug*. Washington, D.C.: Pharmaceutical Manufacturers Association, July 1987.

I. PROTECTING INTELLECTUAL PROPERTY

Adelman, Martin J. "The Supreme Court, market structure, and innovation: Chakrabarty, Rohm and Haas." *The Antitrust Bulletin*, Summer 1982, pp. 457-479.

"Asia Bows to U.S. Pressure For Crackdown on Copyright Pirates." *The Christian Science Monitor*, 17 December 1987.

"Biotechnology Advances Make Life Hard for Patent Office." *The New York Times*, 17 April 1988.

"Biotechnology Lags Despite Success." *The New York Times*, 1 January 1988.

Dingell, Representative John D. Speech to the Association of Biotechnology Companies, 29 March 1988.

Congressional Record. "Proceedings and Debates of the 100th Congress, First Session." Washington, D.C.: 4, 19 February 1987.

Hamburg, C. Bruce. "Patentability of Living Multicellular Life Forms." *Patent and Trademark Review*, Vol. 81, No. 1, 1983, pp. 28-31.

Lautenberg, Senator Frank R. "Introduction of the Process Patent Act of 1987 in the U.S. Senate." *Congressional Record*, Vol. 133, No. 25, 19 February 1987.

_____. "Introduction of the Intellectual Property Rights Enforcement Amendments of 1987 in the U.S. Senate." *Congressional Record*. Vol. 133, No. 17, 4 February 1987.

National Science Foundation. *Congressional Report: 100th Congress, First Session*. Washington, D.C.: Office of Legislative and Public Affairs, January 1988.

"Patent for Genetically Altered Mouse Opens Era for Research, Spurs Protest." *Wall Street Journal*, 13 April 1988.

Pharmaceutical Manufacturers Association. "PMA Seeks Trade Protection In Brazil, Thailand." Washington, D.C., July 1987.

_____. "PMA Files Trade Petition Against Chile." *PMA Newsletter*, 29 February 1988, p. 6.

_____. "South Korea Has Failed to Adhere to Patent Agreement, PMA Charges." *PMA Newsletter*, 14 March 1988, p. 4.

U.S. House of Representatives, Committee on the Judiciary. *Patents and the Constitution: Transgenic Animals*. (Hearings before the Subcommittee on Courts, Civil Liberties, and the Administration of Justice of the Committee on the Judiciary, House of Representatives, 100th Congress, First Session, June 11, July 22, August 21 and November 5, 1987, Serial No. 23.) Washington, D.C.: U.S. Government Printing Office, 1988.

U.S. International Trade Commission. *Foreign Protection of Intellectual Property Rights and the Effect on U.S. Industry and Trade*. Washington, D.C., February 1988.

Watson, Gary S. "The Patentability of Living Organisms." *American Business Law Journal*, Vol. 20, 1982, pp. 93-102.

"Wounded by Patent Piracy . . . Vexed by Tape Technology; U.S. Laws Offer Less Protection Than Those of Major Trading Partners." *The New York Times*, 13 May 1987.

II. EMPOWERING FDA

Bazell, Robert. "Dying for Drugs." *The New Republic*, 9 November 1987.

Dingell, Representative John D. Speech.

"FDA Getting Tougher on Sloppy Drug Applications." *Drug Topics*, 1 February 1988, p. 36.

"FDA Puts New Heart Drug on Hold: A surprise decision by the FDA to withhold approval of TPA, a potent clot-dissolving drug, highlights a scientific debate among cardiologists." *Science*, Vol. 237, 3 July 1987.

Food and Drug Administration. *A Plan For Action*. Rockville, Md., 1985.

_____. *A Plan For Action: Phase II*. Rockville, Md., 1987.

_____. *From Test Tube To Patient: New Drug Development in the United States*. Rockville, Md., January 1988.

_____. *New Drug Evaluation: Statistical Report* (Annual). Document Management & Reporting Branch, Office of Management, in cooperation with the Center for Drugs and Biologics, Rockville, Md., 1979-1987.

_____. *Statistical Report*. Annual, 1979-1987

Flannery, Ellen J. "Should It Be Easier or Harder to Use Unapproved Drugs and Devices?" *Hastings Center Report*, February 1986, pp. 17-23.

General Accounting Office. *FDA Drug Approval — A Lengthy Process That Delays the Availability of Important New Drugs*. Washington, D.C., May 1980.

Gilston, Samuel M. "FDA's Robert Temple: Examining the Drug Review Process." *Medical Advertising News*, 15 June 1984.

"Go-Ahead for a Wonder Drug." *Time*, 23 November 1987.

Grabowski, Henry. "Legislation, Regulation and Innovation." Remarks at the seminar *New Jersey and the Pharmaceutical Industry*. Washington, D.C., 20 June 1985.

Hanson, R.W. "The Pharmaceutical Development Process: Estimates of Development Costs and Times and the Effects of Proposed Regulatory Changes." R.A. Chien, ed. *Issues in Pharmaceutical Economics*. Lexington, Ma.: Lexington Books, 1979.

Hodgson, Thomas A., and Kopstein, Andrea N. "Health Care Expenditures for Major Diseases in 1980." *Health Care Financing Review*, Summer 1984, Vol. 5, No. 4, pp. 1-12.

Hutt, Peter Barton. "Investigations and Reports on the Food and Drug Administration." Food and Drug Law Institute: *Food and Drug Law*, 75th Anniversary Vol. 27, 1984.

Kiely, Thomas. "Rushing Drugs to Market." *Technology Review*, Aug./Sept. 1987.

McMahon Commission Report. *Report of the Commission on the Federal Drug Approval Process*. March 1982.

National Commission for Health Certifying Agencies. *Issues in Pharmaceutical Manufacturers' Current Relations With the FDA Office of Drug Research and Review*. October 1983.

National Pharmaceutical Council. *The Effectiveness of Medicines in Containing Health Care Costs*.

"Outlook, New Drug Development." *Quality Care Insights*, Spring 1987, pp. 6-7.

Pharmaceutical Manufacturers Association. "Drug Approval — 1986 Statistical Review." Washington, D.C., May 1987.

____. *1985-1986 PMA Annual Survey*.

____. *Facts At A Glance*.

____. *Fulfilling The Promise*.

____. *"Drug Approval — Development and Approval Requirements."* Washington, D.C., May 1987.

____. *Report on FDA Staffing and Funding Trends in New Drug Approval Process*. Based on data presented before the House Committee on Appropriations and FDA's *New Drug Evaluation Project Briefing Book*. 29 October 1984.

____. "Survey to Determine Development Time for Drugs Approved in 1986." January 1987.

U.S. House of Representatives, Committee On Science and Technology. *Final Report, Commission on the Federal Drug Approval Process*. Washington, D.C., October 1982.

U.S. Patent and Trademark Office. *Technology Assessment and Forecast Report: Counts by Class by Year*. U.S. Department of Commerce, 1987.

Vaill, Peter B. *A Study of the New Drug Evaluation Process in the Bureau of Drugs, Food and Drug Administration*. Department of Health and Human Services, 10 March 1984.

"World Drug Introductions." *Scrip*. Various issues (1982-1986 figures).

III. ENACTING TORT REFORM

American Tort Reform Association. *Successful Tort Reform Efforts of 1986 and 1987*. Washington, D.C., January 1988.

Huber, Peter. *Liability: The Legal Revolution and Its Consequences*. New York: Basic Books, 1988.

Institute of Medicine. *Vaccine Supply and Innovation*. Washington, D.C.: National Academy Press, 1985.

Jury Verdict Research, Inc. *Current Award Trends*. Solon, Ohio: Jury Verdict Research, Inc., 1988.

Kakalik, James S. and Nicholas M. Pace. *Costs and Compensation Paid in Tort Litigation*. Santa Monica, Ca.: The RAND Corporation, 1986.

Omnibus Health Act of 1986. P.L. no. 99-660, 100 Stat. 3743 (codified as amended in scattered sections of 21 and 42 U.S.C.).

The Conference Board. *The Impact of Product Liability*. Report No. 908. 12 April 1988.

"What's New in Vaccines." *The New York Times*, 15 May 1988.

White, Craig C., M.D., et al. "Benefits, Risks and Costs of Immunization." *American Journal of Public Health*.

IV. SUPPORTING RESEARCH

"A Lengthy Debate Likely on Ways to Split Funds for Campus Facilities." *The Chronicle of Higher Education*, 15 July 1987.

CORETECH. *National Research and Development Policies*.

"Congress Considers Upgrading Labs." *Science*, 24 July 1987, pp. 351-352.

Dingell, Representative John D. Speech.

"Gene Squad: Japanese Now Target Another Field the U.S. Leads: Biotechnology." *Wall Street Journal*, 17 December 1987.

General Accounting Office. *Constraints Perceived by Federal Laboratory and Agency Officials to Technology Transfer*. RCED-88-116BR March 1988.

"Government Gives Scientists the Royal Treatment." *Government Executive*, March 1988, pp 28-32.

"H.R.1905: Selling Bricks and Mortar to Congress." *The Scientist*, 10 August 1987.

Japanese Ministry of International Trade and Industry (MITI). "Technical Development Measures of Ministry of International Trade and Industry." English translation of the R&D budget for MITI. Tokyo: National Science Foundation, 17 August 1987.

"Japan's Push in Pharmaceuticals." *Fortune*, 20 July 1987, pp. 85-86.

National Heart, Lung and Blood Institute. "Collaboration with the Private Sector." January 1988.

National Institutes of Health. *Data Book*.

____. *Then and Now: Biomedical Science in 1887 and Today*.

"National Labs, At Your Service." *High Technology*, July 1985, pp. 39-44.

"National R&D Policy: An Industrial Perspective." Adapted from Roland W. Schmitt, Keynote Speech at the National Conference on the Advancement of Research, 10 October 1983. *Science*, 15 June 1984, pp. 1206-1209.

U.S. Congress. *National Science Foundation Authorization Act, Calendar No. 299*. 100th Congress, 1st Session, Washington, D.C., 1987.

National Science Foundation. *Science and Engineering Indicators — 1987*.

____. *Annual Report 1986*.

____. *Basic Research*.

_____. *Congressional Report*.

_____. "Investment In Health Care Innovation."

_____. "Testimony of Mr. Erich Bloch." 9 March 1987.

_____. "Testimony of Mr. Erich Bloch." 25 June 1987.

_____. "Testimony of Mr. Erich Bloch." 2 December 1987.

Office of Science and Technology Policy. *Report of the White House Science Council*.

Office of Technology Assessment. *Research Funding as an Investment*.

"Patent Policy Changes Stimulating Commercial Application of Federal R&D." *Research Management*, May-June 1986.

Pharmaceutical Manufacturers Association. *Annual Survey*.

_____. *Facts At A Glance*.

_____. *Fulfilling The Promise*.

"Reagan Signs Order Promoting Transfer of Federally Funded Inventions." *Bureau of National Affairs: Daily Report for Executives*, 14 April 1987.

"Reviving the Spirit of Enterprise: Role of the Federal Labs." *Physics Today*, January 1988, pp. 42-50.

Sims, Calvin. "Business - Campus Ventures Grow." *The New York Times*, 14 December 1987.

"The U.S. Shares Its Know-How." *Chemical Week*, December 1986, p. 12.

U.S. Congress. *H.R.1905. University Research Facilities Revitalization Act of 1987*. 100th Congress, 1st Session, Washington, D.C., April 1987.

U.S. Congress. *Technology Transfer Act*. Public Law 99-502. 20 October 1986.

White, Robert M. "Technological Competitiveness and Chemical Engineering." *Chemical Engineering Progress*, January 1988, pp. 24-26.

"Will Old Machines Kill New Ideas? The Poor State of University Labs May Be Creating a Research Crisis." *The New York Times*, 24 May 1987.

V. REVITALIZING SCIENCE EDUCATION

"American Laboratories, Foreign Brains." *The New York Times*, 19 July 1987.

Barber, Elinor G., and Robert P. Morgan. "Impact of Foreign Graduate Students."

"Business Teaching 3R's to Employees in Effort to Compete." *The New York Times*, 1 May 1988.

"Companies Move to Rescue School Science." *Science*, 28 September 1987, pp. 1456-1457.

CORETECH. *National Research and Development Policies*.

Educational Testing Service. "Table of Candidate Grade Distributions." Princeton, N.J.: 1977, 1984, 1987.

"Finding Answers to the Science Teaching Crisis." *The New York Times*, 6 April 1986.

"Foreign Engineers on Rise." *Science*, 29 January 1988, p. 455.

"How to Smarten Up the Schools." *Fortune*, 1 February 1988, pp. 86-94.

International Association for the Evaluation of Educational Achievement. *Science Achievement in 17 Countries*. Elmsford, N.Y.: Pergamon Press, March 1988.

"Mounting Competition For College Teachers." *The New York Times*, 4 December 1987, sec. 12, p. 28.

National Science Foundation. *Annual Report 1986*.

____. *Basic Research*.

____. *Congressional Report*.

____. *Human Talent For Competitiveness*. Washington, D.C., 1987.

____. "Testimony of Mr. Erich Bloch." 9 March 1987.

____. "Testimony of Mr. Erich Bloch." 2 December 1987.

National Science Teachers Association. "The Survey Analysis of U.S. Public and Private High Schools - 1985 86." March 1987.

Office of Science and Technology Policy. *Report of the White House Science Council*.

"Panel Sees Decline in Undergraduate Education." *Science*, 11 April 1986, p. 153.

National Science Foundation, Science and Engineering Education Sector Studies Group. *Selected Data on Graduate Science Engineering Students and Postdoctorates by Citizenship*. Washington, D.C., September 1987.

Steen, Lynn Arthur. "Mathematics Education: A Predictor of Scientific Competitiveness." *Science*, 17 July 1987, p. 251.

U.S. Department of Labor. *The Bottom Line: Basic Skills in the Workplace*. Washington, D.C.: U.S. Department of Education, 1988.

"Wanted: 1 Million Schoolteachers." *The New York Times: Education Life*. (Special Supplement) 4 December 1987, sec. 12, p. 28.

Westheimer, F. H. "Are Our Universities Rotten at the 'Core'?" *Science*, 5 June 1987, pp. 1165-1166.

"Will Old Machines Kill New Ideas?" *The New York Times*.

VI. RESTRUCTURING TAX POLICY

Baily, Martin Neil, and Robert Z. Lawrence. *Tax Policies For Innovation and Competitiveness*. Washington, D.C.: The Council on Research and Technology, 1987.

"Broader Tax Break On Research Urged For Multinationals." *The Wall Street Journal*, 6 April 1987.

Bureau of National Affairs. *R&D: Treasury Backs Permanent Tax Credit But Is Undecided on Specific Proposal*. 6 April 1987.

CORETECH. *National Research and Development Policies*.

National Science Foundation. *Congressional Report*.

Office of Science and Technology Policy. *Report of the White House Science Council*.

Pharmaceutical Manufacturers Association. *Annual Survey*.

____. *Facts At A Glance*.

____. *Fulfilling The Promise*.

"Treasury Suggests Permanent and Restructured R&D Credit." *Tax Notes*, 13 April 1987.

QUOTATIONS: SOURCES

Bloch, Erich. Statement to the Joint Economic Committee, U.S. Congress, 2 December 1987.

Bogorad, Lawrence. Opening remarks. *R&D in FY 1988: R&D Policies, Budgets and Economic Competitiveness*.

Brademas, John. Address to the Sigma Xi Centennial Meeting at the National Academy of Sciences. 25 October 1986.

Bradley, Senator Bill. Special communication.

Danforth, Senator John. Senate floor statement, 9 August 1986.

DeConcini, Senator Dennis. Remarks, PMA annual meeting, 1988.

Dingell, Representative John D. Remarks to the Association of Biotechnology Companies, 29 March 1988.

Dole, Senator Robert. Special communication.

Fish, Representative Hamilton. House floor statement, 21 April 1988.

Foley, Representative Thomas. Special communication.

Kastenmeier, Representative Bob. House floor statement, 20 May 1986.

Lautenberg, Senator Frank. Senate floor statement, 26 April 1988.

Leahy, Senator Patrick. Senate floor statement, 9 August 1986.

Lujan, Representative Manuel, Jr. House floor statement, 9 December 1985.

Press, Frank. Address to members of the National Academy of Sciences, 26 April 1988.

Rockefeller, Senator Jay. Senate floor statement, 3 October 1986.

Schneider, Representative Claudine. In *American Politics*, November-December 1987.

Shakhashiri, Bassam Z. "International Survey Gives U.S. a Failing Grade in Science Education." National Science Foundation News, 29 February 1988.

Wyngaarden, James B., M.D. *A Century of Science for Health*. National Institutes of Health, 1987.

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